

# **AGENDA ITEM # 6**

**MEDICAL BOARD STAFF REPORT**

DATE REPORT ISSUED: April 25, 2008  
ATTENTION: Board Members  
DEPARTMENT: Medical Board of California  
SUBJECT: Consideration of petition to adopt regulations defining the supervision of nurses  
STAFF CONTACT: Janie Cordray

REQUESTED ACTION:

Accept or deny the petition filed under Government Code Section 11340.6 by The American Society for Dermatologic Surgery Association (ASDSA).

STAFF RECOMMENDATION:

Staff recommends that the Board deny the ASDSA petition at this time, pending the outcome of AB 2398 (Nakanishi) and SB 1454 (Ridley-Thomas). If AB 2398 is successful, in addition to setting supervision standards, it may provide a greater deterrent, as it authorizes significant fines and possible jail confinement for violations.

EXECUTIVE SUMMARY:

Under Section 11340.6 of the Government Code, interested parties may petition state agencies to promulgate regulations. The ASDSA has petitioned the Board to promulgate regulations that would require direct (on-site) supervision of nurses performing cosmetic procedures. Presently, the law allows nurses to be delegated these procedures under standing protocols, called "standardized procedures," without physicians being physically present. (Physicians must conduct an appropriate examination of the patient before delegating the procedure, but need not be present at its performance.)

Specifically, the ASDSA proposes the Board adopt the following regulation:

- (a) *Any physician who delegates the performance or administration of any cosmetic medical procedure or treatment shall provide direct supervision of such procedure or treatment.*
- (b) *"Direct supervision" shall mean that a physician must be on-site and available to the registered nurse for immediate consultation at the time of performance of, or administration of, the procedure or treatment.*
- (c) *As used in this article, "cosmetic medical procedure" and "cosmetic medical treatment" means a medical procedure or treatment that is performed to alter or reshape normal structures of the body solely in order to improve appearance.*

The petition also asks for additions to the Board of Registered Nursing (BRN) regulations. While the BRN may, after actions taken by the Medical Board or passage of legislation, choose to amend their regulations for consistency, the Medical Board has no authority to grant that portion of the ASDSA request.

As the members may recall, at the November 2 Board meeting, members were presented with a report on the public forums held jointly by the Medical and Nursing Boards on the use of lasers for cosmetic procedures pursuant to SB 1423 (Figueroa; Ch. 873, Stats. of 2006.) A written report on the law and requirements of supervision was prepared for the members. The conclusion from the testimony gathered

from the forums was that any impediment to public safety was not due to a lack of law and regulations; instead, it was the lack of compliance and enforcement of the laws and regulations already in existence. The Board agreed to work toward greater enforcement and the education of the profession and consumers. In addition, the Board directed staff to write the BRN and continue to work with them to strengthen enforcement and education efforts.

Since the filing of the petition, Assembly Member Nakanishi introduced AB 2398, and Senator Ridley Thomas introduced SB 1454. Both bills would have implications for the supervision of allied health professionals delegated laser procedures. In addition, AB 2398 sets limits of the number of sites supervised, and establishes significant fines of up to \$25,000 per violation, as well as criminal penalties of up to a year of confinement for repeat offenders. SB 1454 would require the board to promulgate regulations for supervision of laser procedures by July 1, 2009.

FISCAL CONSIDERATIONS:

While there is no substantial fiscal impact to the Board for the promulgation of regulations, there is no additional revenue provided for its enforcement. As discussed at the November 2 Board meeting, violations relating to cosmetic procedures, absent any patient harm, are generally not investigated or prosecuted due to lack of resources.

PREVIOUS MBC AND/OR COMMITTEE ACTION:

At the November 2 Board meeting, members were presented a report on the use of lasers for cosmetic procedures. In summary, the conclusion of the testimony received at the joint Medical and Nursing Board forums was that the problem of patient safety was not due to insufficient laws or regulations, but due to a lack of compliance and enforcement of current laws. The lack of enforcement was caused by limited resources. For that reason, it was the decision of the Board to not seek legislation or promulgate new regulations; instead, it would seek additional investigator positions and focus its efforts on enforcement and education of the profession and consumer.

# WILKE, FLEURY, HOFFELT, GOULD & BIRNEY, LLP

400 CAPITOL MALL  
TWENTY - SECOND FLOOR  
SACRAMENTO, CALIFORNIA 95814

PHILIP R. BIRNEY\*  
SCOTT L. GASSAWAY  
ERNEST JAMES KRITIL  
ROBERT R. MIRKIN  
MATTHEW W. POWELL  
STEPHEN K. MARMADUKE  
DAVID A. FRENZNICK  
JOHN R. VALENCIA  
KELLI M. KENNADAY  
ANTHONY J. DeCRISTOFORO  
ROBERT F. TYLER  
MICHAEL G. POLIS  
DANIEL L. EGAN  
DANIELLE M. GUARD  
DANIEL L. BAXTER

TELEPHONE  
(916) 441-2430

TELECOPIER  
(916) 442-6664

RICHARD H. HOFFELT  
WILLIAM A. GOULD, JR.  
GENE E. PENDERGAST, JR.  
THOMAS G. REDMON  
RONALD R. LAMB

KIM JOHNSTON  
MEGAN A. LEWIS  
ERIN E. WEBER  
TREVOR L. STAPLETON  
ANTHONY R. EATON  
CRAIG A. CARNES, JR.  
MARISSA L. DRAGOO

February 15, 2008

\* PROFESSIONAL CORPORATION

**BY CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

JVALENCIA@WILKEFLEURY.COM

Ms. Barbara Johnston  
Executive Director  
Medical Board of California  
1426 Howe Avenue, Suite 54  
Sacramento, CA 95825-3236

Re: Petition for Adoption of Regulation Defining "Physician Supervision"

Dear Director Johnston:

The Medical Board of California (MBC) and the California Board of Registered Nursing (BRN) have now completed their series of 2007 hearings into the matters required by SB 1423 (Figueroa; Ch. 873, Stats. of 2006). That law required both agencies "...to review issues and problems surrounding the use of laser or intense light pulse devices for elective cosmetic procedures by physicians and surgeons, nurses, and physician assistants." Now, the agencies are required to adopt regulations relating to that practice on or before January 1, 2009.

On behalf of the American Society for Dermatologic Surgery Association (ASDSA), the CalDerm and the Osteopathic Physician and Surgeons of California (the "Petitioners"), the purpose of this letter is to petition the Medical Board of California ("the Board") pursuant to Government Code section 11340.6 to adopt a new regulation defining "physician supervision" as it relates to the performance or administration of any elective cosmetic medical procedure or treatment (i.e., a medical procedure or treatment performed to alter or reshape normal structures of the body solely in order to improve appearance) by an eligible non physician upon delegation by a physician and surgeon. The Medical Board has authority to adopt regulations pursuant to both Business and Professions Code sections 2018 and 2023.5 as recently added. A proposed version of the regulation is attached hereto as Exhibit "A". The basis for this petition is outlined below. Petitioners incorporate by reference as support for this petition, the public record governed by the three (3) joint public forums conducted by the Medical Board of California and the Board of Registered Nursing on August 31, September 13 and October 31, 2007 respectively.

### **CURRENT MEDI-SPA PRACTICES NECESSITATE REGULATORY CLARIFICATION**

Alternative patient treatment sites, often called “medi-spas,” have become a major, and often misleading, presence in the medical cosmetic skin care field – a phenomenon witnesses before the Board regularly referred to as an “industry” serving “clients.” They may be freestanding locations, or are routinely located in potential high-volume locales such as shopping malls or centers.

“Medical spas are marketing vehicles for medical procedures. If they are offering medical procedures, they must be owned by physicians. The use of the term ‘medical spa’ is for advertising purposes to make the procedures seem more appealing. In reality, however, it is the practice of medicine.”

The Medical Board, however, is concerned when medicine is being marketed like a pedicure, and consumers are led to believe that being injected, lasered, and resurfaced requires no more thought than changing hair color.

Medical treatments should be performed by medical professionals only. There is risk to any procedure, however minor, and consumers should be aware of those risks. While it is illegal for unlicensed personnel to provide these types of treatments, consumers should be aware that some persons and firms are operating illegally. Cosmetologists, while licensed professionals and highly qualified in superficial treatments such as facials and microdermabrasion, may never inject the skin, use lasers, or perform medical-level dermabrasion or skin peels. Those types of treatments must be performed by qualified medical personnel. In California, that means a physician, or a registered nurse or physician assistant under the supervision of a physician.” (*Medical Spas – What You Need to Know*, Medical Board of California on-line guidance, January 2008; emphasis added)

A recent *New York Times* article reported, “Of the 11.5 million cosmetic procedures performed in 2006, more than four in five were noninvasive treatments, according to the aesthetic plastic-surgery society. From 1997 to 2006, the number of surgical cosmetic procedures rose 98 percent, and noninvasive treatments jumped 747 percent. (Janet Morrissey, *Having a Little Work Done (At the Mall)*, Jan. 13, 2008)

Similar investigative reports have appeared over time. (Rhonda L. Rundle, *Getting Botox at the Mall*, THE WALL STREET JOURNAL, Jan. 3, 2006 at D1; see also, Janine S. Pouliot, *Spa Savvy*, MILWAUKEE MAGAZINE, December 2004, p. 36, attached as Exhibit “B”; see also Exhibit “C”, which consists of a number of cosmetic skin care advertisements; see also Patricia King, *Prescription for Pampering*, LA TIMES, Sept. 20, 2004, attached as Exhibit “D”;

Indeed, “nonsurgical cosmetic procedures in 2004 increased 51 percent from 2003 according to the American Society for Aesthetic Plastic Surgery.” James Rizzuto, *Myths & Truths of MediSpas*, SOUTHERN CALIFORNIA PHYSICIAN, July 2005 at p. 23.

The evident allure of a medi-spa is that an individual may receive consumer “services” such as facials, pedicures, and hair styling in the same setting as medical treatments such as collagen injections, Botox® injections, and laser skin treatments, in a single setting, quite possibly on impulse. Emphasizing the so-called “cosmetic” nature of such medical care, the direct mail, newspaper and Internet advertising for entities ranging from the presently-active Advanced Laser Clinics, and the now-defunct Nuvo International Laser Skin Centers, successfully prosecuted by the Sacramento County District Attorney (Exhibit “E”) offer medical treatments including laser hair removal, vein removal, microdermabrasion, photofacial and photo rejuvenation treatments, and collagen, Botox® and Restylane® injections. Advertising, as the enclosed exhibits reflect, is often openly and patently in violation of the provisions of the Medical Practice Act, even to the point of offering suspect, non-FDA approved “medications” such as “Lipo-Dissolve” for cosmetic medical care.

Despite the many services offered at medi-spas that are clearly offers of medical care, so-called cosmetic medical procedures, when actually performed by a health care professional, are often performed without any direct supervision by a physician. Indeed, out of 19 Sacramento and Bay Area medi-spas contacted in a random survey, only 6 indicated a physician was on-site at all times when cosmetic medical procedures are performed. (See Declaration of Marissa Ramos, Esq., attached as Exhibit “F”).

Current California regulatory guidance leaves unclear whether a physician must directly supervise allied health professional when delegating the type of cosmetic medical procedures that are provided in “medi-spas,” including treatment with lasers or intense pulse light (IPL). This lack of definitive standard for physician supervision is subjecting patients to risk and actual injury.

As stated in a recent academic article, “In the case of the laser use in a spa, the financial incentives for delegation are further enhanced by the nature of the business model, which resembles a retail store rather than a medical practice, and to a greater extent than in a physician practice, service providers may be compensated on an incentive basis...the pressure to ‘convert’ all consultations into treatments may result in poor patient selection, which in turn may dramatically increase the rate of adverse events.” (M. Alam, MD; J.S. Dover, MD, K.A. Arndt, MD; *Use of Cutaneous Lasers and Light Sources: Appropriate Training and Delegation*, SKIN THERAPY LETTER, 2007; 12(5):5-9)

“Physicians may use lasers or intense pulse light devices. In addition, physician assistants and registered nurses (not licensed vocational nurses) may perform these treatments under a physician's supervision. Unlicensed medical assistants, licensed vocational nurses, cosmetologists, electrologists, or estheticians may not legally perform these treatments under any circumstance, nor may registered nurses or physician assistants perform them independently, without supervision.” (*Use of Mid-level Practitioners for Laser, Dermabrators, Botox, and Other Treatments*, Medical Board of California, January 2008 online guidance originally published in the October 2002 *Action Report*)

The record of testimony presented before the agencies in their 2007 hearings graphically bears out the ongoing and continuous, unsupervised acts and omissions that are leading to patient injury in California. Rather callous counter-testimony attempted to minimize such injuries. The 2007 testimony, recounting cases arising throughout 2007 and 2006, are only the most recent occurrences in a pattern of patient injuries in California and elsewhere throughout the country.

In late 2004, Karin Gilliam was badly burned by a laser hair removal procedure at Nuvo International. In June 2005, she continued to have scars and white streaks on her face. Similarly, KRON-TV 4 interviewed Elealah Ruff who also sought laser hair removal treatment at Nuvo International and was burned. She said that minutes after her session began, “she noticed a tingling, then a burning. The laser ripped away her skin, leaving it bloody and raw. ‘It was like black streaks all over my face.’” (State Cracks Down on Nuvo International, attached as Exhibit “G”.) Further investigation by KRON-TV confirmed that a doctor was rarely on site at the Nuvo International clinic from which Ms. Gilliam received treatment. (*Ibid.*)

The potential risks to individuals who receive unsupervised treatments in medi-spas are serious and not simply cosmetic. In 2005, a college student in North Carolina died following application of a numbing cream of 10 percent lidocaine prior to her laser appointment. (Beth Kapes, *Who’s managing medispas?*, COSMETIC SURGERY TIMES, April 2005, attached as Exhibit “H”.) Sadly, this young student was not the first to die as a result of insufficient supervision. In January 2002, a woman applied anesthetic cream to her legs and wrapped them in cellophane several hours before a laser hair removal appoint. She suffered a seizure - after living nearly two years in a coma dependent on a respirator – and died in November 2003. (*Ibid.*)

In short, the imprecision of current California law unnecessarily places individuals such as these at risk of incurring unnecessary serious and lasting injuries, including the potential for death.

**ALL COSMETIC MEDICAL PROCEDURES SHOULD BE DIRECTLY SUPERVISED  
BY A LICENSED PHYSICIAN AND SURGEON**

The Medical Board of California working, to the extent necessary with the Board of Registered Nursing, has the authority and ability to reduce the risk of injury to California patients who must be regarded as such – and not merely as “clients” - by enacting clear standards for the direct supervision of allied health professionals who perform cosmetic medical procedures. Indeed, some standards exist for the delegation of elective cosmetic medical procedures from a physician to all allied health professionals in California. For instance, a Medical Assistant may not inject collagen, or Botox®, or utilize lasers or intense light devices to remove hair, spider veins, wrinkles, scars, moles, tattoos or other blemishes. (16 CCR §§1366, sub(b)(2); 1366.4.) By comparison, a Physician Assistant may perform an array of cosmetic medical procedures “consistent with the supervising physician's specialty or usual and customary practice,” but only under the in-person supervision of a physician, undermined by the broad alternative that a

physician may be available by electronic communication. (16 CCR §1399.545.) This definition, augmented by additional required protocols, may not adequately ensure that a physician is integrally involved with the care and treatment of a patient by a physician assistant.

By comparison, of all allied health professionals, physicians are allowed to delegate the broadest number of responsibilities to registered nurses. As representatives for corporate owners of “medi-spa” chains in California testified before the Boards, however, such corporate entities are at the forefront of exploiting the manner whereby, and the settings in which, such delegation may occur by promoting cosmetic medical procedures at medi-spas with inadequate physician supervision. By the same token, numerous “aesthetic nursing” representatives advocated for unsupervised or minimally supervised performance of elective cosmetic medical services – essentially advocating for an independent cosmetic practice virtually afforded by the “medi-spa” setting.

These positions were advanced despite the basic requirement that the only means by which such functions exceeding the usual scope of practice may be performed – pursuant to written “standardized procedures” in an organized health care system (i.e., generally speaking, a clinics, home health agencies, physicians' offices and public or community health services). (16 CCR §1470-1474)

Standardized procedures, if even validly applicable for a “medi-spa” setting, let alone actually to be found governing health care services in such settings, are left to be crafted by the promoters of medical care in these situations, stretching existing regulation beyond recognition. (16 CCR §1471(c): §1472). Not surprisingly, the specified scope of supervision required for the performance of the particular standardized procedure functions, routinely falls short of requiring immediate supervision of a physician. Standardized procedure guidelines set forth in regulation require specification of the scope of supervision required for performance of standardized procedure functions, for example, immediate supervision by a physician. (16 CCR §1474(b) (7)) Yet, this tier of patient protection is mitigated by online agency guidance relating to lesser levels of patient protection that may be established, “Each standardized procedure shall:...Specify the scope of supervision required for performance of standardized procedure functions, for example, telephone contact with the physician. (*AN EXPLANATION OF THE SCOPE OF RN PRACTICE including standardized procedures*, Board of Registered Nursing, NPR-B-03 06/95, REV. 07/97; emphasis added)

Generalized and nonspecific “standardized procedures” leading to the performance of cosmetic medical procedures when a physician is not present in a treatment setting is directly at odds with how medical treatment and the practice of medicine are defined in California law. This casual handling of physician supervision has led to the routine establishment of “independent” practices by allied health professionals in settings offering cosmetic medical care. As a result, as the examples provided explicitly indicate, patients are being injured, or at the very least, are subjected to unnecessary risk of injury, as a consequence.

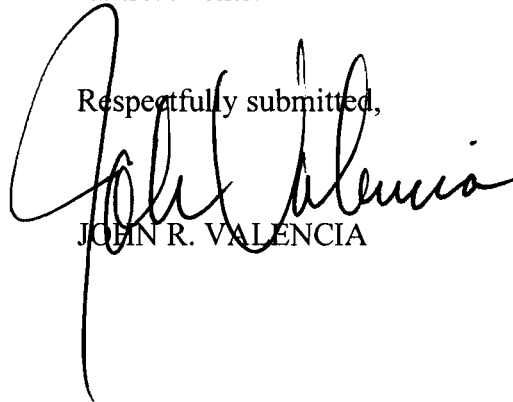


February 15, 2008

Page 6

Therefore, we respectfully request that the Board (or Boards) adopt the proposed version of the regulation attached hereto as Exhibit A as necessary to ensure the safe treatment of California patients who may seek cosmetic medical treatments.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "John R. Valencia". The signature is fluid and cursive, with a large initial "J" and "V".

JOHN R. VALENCIA

Enclosures (Exhibits "A" – "I")

cc:

Ruth Ann Terry, MPH, RN  
Executive Office  
California Board of Registered Nursing  
1625 North Market Blvd,  
Suite N217  
Sacramento, CA 95834

Elberta Portman, Executive Officer  
Department of Consumer Affairs  
Physician Assistant Committee  
1424 Howe Avenue, Suite 35  
Sacramento, CA 95825

JRV:jlc

339689.1

# EXHIBIT A

## **Exhibit “A”**

### **Proposed Regulatory Provisions**

#### **Medical Board of California – Regulation – Add Title 16 CCR Section To be numbered**

“\_\_\_\_\_. (a) Any physician who delegates the performance or administration of any cosmetic medical procedure or treatment shall provide direct supervision of such procedure or treatment.

(b) “Direct supervision” shall mean that a physician must be on-site and available to the registered nurse for immediate consultation at the time of performance of, or administration of, the procedure or treatment.

(c) As used in this article, “cosmetic medical procedure” and “cosmetic medical treatment” means a medical procedure or treatment that is performed to alter or reshape normal structures of the body solely in order to improve appearance.

#### **Board of Registered Nursing – Regulation – Add Title 16 CCR. Section 1474.1**

1474.1 (a) Except as otherwise permitted in Section 1474, all cosmetic medical procedures and cosmetic medical treatments delegated by a physician to a registered nurse shall require direct supervision by a physician.

(b) Direct supervision shall mean that a physician must be on-site and available to the registered nurse for immediate consultation at the time of administration of the cosmetic medical procedure or cosmetic medical treatment.

(c) As used in this article, “cosmetic medical procedure” and “cosmetic medical treatment” means a medical procedure or treatment that is performed to alter or reshape normal structures of the body solely in order to improve appearance.

#### **Physician Assistants – Regulation – Add Title 16 CCR Section 1399.To be numbered**

(a) Except as otherwise permitted in Section 1399.545, all cosmetic medical procedures and cosmetic medical treatments delegated by a physician to a physician assistant shall require direct supervision by a physician.

(b) Direct supervision shall mean that a physician must be on-site and available to the physician assistant or immediate consultation at the time of administration of the cosmetic medical procedure or cosmetic medical treatment.

(c) As used in this article, "cosmetic medical procedure" and "cosmetic medical treatment" means a medical procedure or treatment that is performed to alter or reshape normal structures of the body solely in order to improve appearance.

335829.1

# EXHIBIT B

# YOURhealth

BY JANINE S. POULIOT

## Spa Savvy

SPAS HAVE VENTURED BEYOND TRADITIONAL SKIN CARE TO CHEMICAL PEELS AND BOTOX INJECTIONS. BUT ARE THEY QUALIFIED?



**YOU GO TO A SPA TO FEEL GOOD.** After a luxurious treatment, you leave refreshed, relaxed, glowing. But these days, many spas are going one step further, no longer limiting their treatments to such pampering as facials and massages — they've now joined the legions of providers offering anti-aging procedures. The once clear demarcation between a doctor's office and a spa has blurred. Now it's common to find similar procedures offered by dermatologists, plastic surgeons, medical spas and even day spas. But are the results the same no matter where you go?

Susan\* doesn't think so. In her mid-40s, Susan wanted to look her best and figured that purchasing a package of treatments at a local spa was the way to do it. "I liked the idea of good-quality skin procedures," she says. So she invested hundreds of dollars to undergo what she thought would be five chemical peels to spruce up her face. The first four proved disappointing. "They were more like regular facials, not peels," she says. So on her last visit, she mentioned it to the esthetician. Unfortunately, she then got more than she bargained for.

"I think she used too high an amount of chemical," says Susan. The results were devastating. "My face was bright

red, like it was burned," she relates. "It felt very hot, fiery hot. My skin literally peeled off in sheets. The skin underneath was so raw it almost looked like I would bleed. And it continued to peel for days."

Unfortunately, Susan didn't have the luxury of staying home to hide her disfigurement. "I had to tell people [at work] I'd had a peel," she says. "It was very bad and very deep."

Susan eventually healed completely and was left without any scarring. But she's more cautious now. She knows to ask plenty of questions before she submits her face to anyone.

**WHILE SUSAN'S EXPERIENCE** is far from the norm, the question of who should perform which skin procedure is a critical one. Should it be a doctor, nurse, esthetician at a physician's office or esthetician at a spa? For the average consumer, it's a confusing world to negotiate.

"I think there is a lot of crossover between what's done in a spa and in a doctor's office," concurs Dr. John Yousif, a plastic surgeon and clinical professor at the Medical College of Wisconsin who is also affiliated with Columbia, St. Mary's-Milwaukee and Froedtert Memorial Lutheran hospitals. "Depending on the procedure, I believe each area has its advantages. But medical procedures should be done by medical people," he says emphatically. "Even when a spa says it has a physician supervising, it could be any kind of a doc-

### BUYER BEWARE

The increasing popularity of nonsurgical cosmetic procedures has led to a growing complacency about where procedures are performed and by whom, according to the American Society for Aesthetic Plastic Surgery. It is the position of ASAPS that procedures such as skin resurfacing or Botox, although nonsurgical, are still medical in nature and should be done under the supervision of a qualified doctor. They recommend the following:

- A medical history should be taken first to avoid allergic reactions and to identify underlying medical conditions that might pose risks.
- An exploration of alternative treatments should be undertaken, including the option of no treatment at all.
- A detailed explanation of the benefits, risks and down time should be given.
- Procedures should be done in sanitary surroundings with sterile equipment.
- There should be emergency plans in place in case of unforeseen complications.
- Follow-up care should be available and offered.

tor – an anesthesiologist can inject Botox. That leaves a lot up to the patient to define who is in charge. I don't think people ask many questions, especially when they're told that the spa does this procedure all the time. They think the regulations will protect them. But there are no regulations about who can do what. I don't think people understand that."

The American Society for Dermatologic Surgery recently launched a campaign warning consumers that "certain cosmetic treatments such as those using lasers, high-tech light devices, chemical peels, soft-tissue fillers [like Botox] and microdermabrasion techniques should be performed by a fully qualified physician or under the direct supervision of a physician."

### CHECK OUT YOUR PROVIDER

To determine whether your esthetician has the proper credentials, go to the Wisconsin Department of Regulation and Licensing Web site ([www.drl.state.wi.us](http://www.drl.state.wi.us)). Click on Business and Design and follow the prompts for esthetician. Click FAQ (Frequently Asked Questions) to learn this, as well as to file a complaint or determine if there are any disciplinary actions against a licensed esthetician.

In addition, in a recent ASDS survey administered to its members, nearly 41 percent reported an increase in patients seeking corrective treatment due to damage caused by untrained non-physicians.

So what it all boils down to is training. But that doesn't automatically translate into requiring the services of a physician. Actually, the ASDS is okay with having some procedures performed by professionals other than a plastic surgeon or dermatologist, as long as a doctor directly oversees the staff. The ASDS position: "Under the appropriate circumstances, a physician may delegate certain procedures to certified or licensed non-physician office personnel."

But of course it's not quite that simple. The ASDS does attach a big proviso: "Specifically, the physician must directly supervise the non-physician personnel to protect the best interest and welfare of each patient. The supervising physician shall be physically present on-site, immediately available and able to respond promptly to any question or problem that may occur while the procedure is being performed."

Thus, a medical spa meets these criteria. According to the International Medical Spa Association, a medical spa "operates under the full-time, on-site supervision of a licensed healthcare provider." This is dif-

*continued on page 67*

# EXTRA! EXTRA!

Best Italian Coastal  
Restaurant of 2004!

-Zagat Survey

Top 20 Restaurants

-Milwaukee Magazine

Top 30 2001-2004

-Milwaukee Journal-Sentinel

LUNCH IN TOWN.

-Milwaukee Magazine

pretentious Passion

-British Weekly

"UNFORGETTABLE EXPERIENCE!"

-Daily News

"Feker's passion feeds the stars."

-Hollywood Reporter

"Excellence costs little at  
IL MITO."

-Los Angeles Times

COME AND SEE WHAT THE  
CRITICS ARE RAVING ABOUT

**IL MITO**

Coastal-Italian Cuisine  
605 WEST VIRGINIA STREET  
414.276.1414  
[WWW.ILMITO.COM](http://WWW.ILMITO.COM)

## WELLNESS WORKSHOP

### How & Why Acupuncture Works

MONDAY, DECEMBER 13, 7-8 P.M.

- See an Acupuncture demonstration performed.
  - Learn why 2 billion people worldwide use this ancient form of healing.
  - Learn what Acupuncture feels like, what it treats and how it works.
  - Speak to Curry Chaudoir - renowned for his successful treatment of various stress related disorders such as digestive disturbances, migraines, headaches, shoulder/neck/back pain, allergies, sinus problems, fatigue depression, PMS, menopause and fibromyalgia.
  - Find out if Acupuncture can help you.
- Acupuncture-the drug-free alternative to healthcare



**Guest Speaker**  
Curry Chaudoir

Diplomate in Acupuncture  
and Chinese Herbal Medicine

Where: Whitefish Bay Public Library Community Room

5420 N. Marlborough Drive

Cost: \$5 per person-advance payment reserves your seat

Contact April at (414) 332-8888 by December 9th.

WORKSHOP IS LIMITED TO THE FIRST 15 CALLERS. CALL TODAY!

## Spa Savvy

continued from page 39

ferent than a day spa, which has no affiliation with the medical community and no licensed healthcare provider on-site. Typically, a day spa specializes in such feel-good treatments as massage, routine facials, hair styling, waxing, manicures and pedicures.

But all spas, regardless of their classification, must employ only licensed estheticians. At least that's the law in Wisconsin (it varies from state to state). In Milwaukee, in order to practice, an esthetician must have a current license from the Wisconsin Department of Regulation and Licensing. To qualify for this critical credential, he or she must have completed at least 450 hours of training over a specified time period in a licensed school and have passed both a written and practical exam given by the state board of examiners.

But a license is only part of the story. Equally important is a thorough understanding of the chemicals and equipment used in all treatments. "Our estheticians go through a nine-month to one-year program at school to learn about skin care, the anatomy of skin, the different types of treatments, techniques and so on," says Deneine Powell, owner of Seven Stones Center for Wellness on Farwell Avenue.

"Our estheticians spend a lot of time refining their techniques," says Powell. "We require everyone who works here to go for additional training at the International Dermal Institute in Chicago." The IDI offers classes worldwide on all aspects of skin care, awarding post-graduate continuing-education credits. "Estheticians have to know what they're doing," says Powell. "They can't mess up someone's face."

**SO WHAT REALLY HAPPENS AT** a plastic surgeon's office vs. a spa? "Plastic surgeons deal mainly with surgery," explains Dr. Ralph Kloehn, a plastic surgeon affiliated with Aurora Health Care and St. Joseph's and Elmbrook hospitals. "They don't do the esthetic medicine. If the nurse is equipped and knowledgeable, she gets more involved in the simple face procedures, in improving the quality of skin. Some plastic surgeons hire an esthetician for their office."

What really sets a spa and a plastic surgeon's or dermatologist's office apart, however, is the degree of the invasiveness of the treatments. Both a doctor and an esthetician can perform a peel. But the doctor can go much deeper into the dermis, resulting in more profound results. A medical spa at a physician's office offers the patient a choice—they can pick a light treatment or a



**Injectables Special**  
\$50 off treatment with mention of this ad.

Reveal Your  
*Inner Beauty*

Evenings available  
Most insurances accepted  
Se habla español

Have  
your procedure now  
and be picture  
perfect by  
the holidays!

Exclusive Distributor for TNS Complex in downtown Milwaukee

## Give Ritz Gift Certificates this Holiday

Available in any denomination.

**\$99 Hair Removal Special**  
**Upper Lip & Chin**

Laser Treatment Reg. \$200  
(up to 8 treatments)



Unmatched experience  
makes Ritz the best choice  
for worry-free treatment.

Only at Ritz is your treatment overseen  
by the person Candela Laser has trusted  
for over five years to train physicians and  
technicians in the use of their lasers.

### FREE INITIAL CONSULTATION

Laser removal of hair, tattoos & skin imperfections  
Botox & Restylane treatments • Microdermabrasion  
Skin care • Rosacea • Acne • Skin rejuvenation  
Psoriasis • Derma-Sound • Age spot removal  
Laser removal of spider veins  
Rejuvi skin care products • Clio Minerals skin care makeup

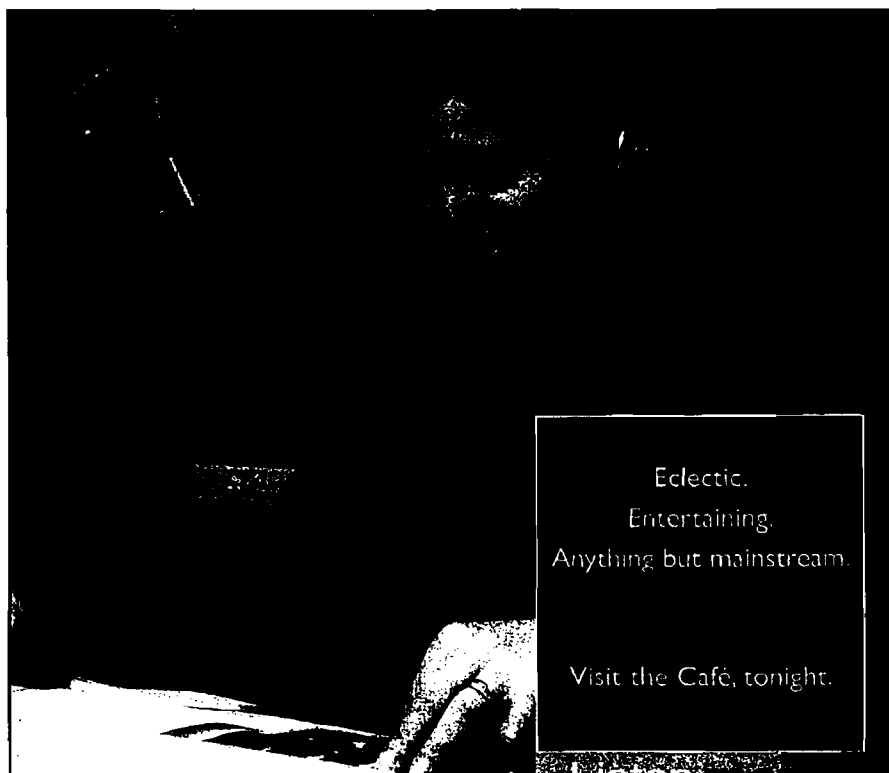
Not valid with any other offers. Offer valid through January 31, 2005

**RitzLaser.com • (262) 754-8800**  
17585 W. North Avenue, Brookfield • Suite 130  
Just west of Ruby Isle in the Dix Building, Brookfield  
©2005 RITZ LASER

**Ritz**  
Laser & Skin Care  
CENTER

THE GOLD STANDARD





Eclectic.  
Entertaining.  
Anything but mainstream.

Visit the Café, tonight.

**Listen More**

[www.wuwm.com](http://www.wuwm.com)

Amanda Shalhoub, Co-Host, "Café Tonight"

For music that isn't top 40 and a format that isn't, well, formatted, come to the Café. On Café Tonight, WUWM invites you to listen to a wide variety of music – some you're familiar with and some you'll be introduced to. Either way, you won't find it elsewhere. There's no doubt that once you visit the Café, you'll continue to Listen More.

Listen to Café Tonight, weeknights 7-10 p.m. on 89.7 WUWM. Play lists and complete program schedule available at [www.wuwm.com](http://www.wuwm.com).

MILWAUKEE PUBLIC RADIO **FM 89.7**  
**WUWM**  
Listen more. Learn more.

UNIVERSITY OF WISCONSIN  
**MILWAUKEE**

**GIFT CERTIFICATES  
AVAILABLE**

**SPA  
EAST TOWN**

A full service salon & spa  
for men & women

718 E. WELLS ST. • 414-271-4247

NOT ALL FACIAL  
REJUVENATION PROCEDURES  
ARE CREATED EQUAL.  
THERE'S MORE FIRE POWER,  
SO TO SPEAK, AT A  
PHYSICIAN'S OFFICE.

heavy-duty one, all at the same location.

"You can start out slowly and see what results you get," says Kloehn. "Take it step by step. If you want more, the doctor is there to use intense pulsed-light lasers or do microdermabrasion. You have the option to do as little or as much as you want. [If you reach] the point where you're ready for surgery, you already have someone in your pocket. You don't have to start over."

But there's an even bigger distinction. Not all facial rejuvenation procedures are created equal, even when they are called by the same name. There's more fire power, so to speak, at a physician's office.

"Lots of times, spas do all the appropriate treatments, like light chemical peels," says Dr. Gretchen Zirbel, dermatologist and clinical instructor at MCW who is affiliated with St. Luke's, Froedtert and Elmbrook hospitals. "But when you get into lasers, you've got two problems. The first, of course, is safety. You don't want to do something that hurts the patient or causes scars."

"But what's more of an issue is that the patient gets a procedure that is really effective. Most laser and microdermabrasion equipment comes in two models: one for a medical facility and a weaker version for a spa. The strongest type may not be available to a spa. Their equipment does not have the capacity to go as high. It's a safety factor."

The more skill and training a provider has, the fewer restrictions the manufacturer sets on what the equipment can do. "We pick-up the knowledge to push the limits," says Zirbel. "We go to other doctors' offices to learn more, we go to medical conferences. We develop an expertise. We can push it to the point where the patient is getting their money's worth but not high enough to cause a scar. This is a hard area to master. It requires the most expertise."

And this, more than anything else, is what sets the spa apart from the doctor's office. It all comes down to the same critical issue: training. "It's difficult to keep on top of the new lasers without visiting other dermatologists and surgeons who actually use them," says Zirbel. "You have to keep up that contact."

The worst place to gather information.

SURE, A DERMATOLOGIST HAS A LICENSE TO PLAY WITH THINGS WE CAN'T. THEIR RESULTS ARE MORE DRAMATIC. BUT NOT EVERYONE NEEDS TO GO TO A DOCTOR'S OFFICE.

according to Zirbel, is the manufacturer's salesman. "They're a poor source. I completely bypass that. Before I buy a laser, I'll share back and forth with a lot of doctors about the problems they've had. That's how we figure out how to do the settings. It allows me to be more aggressive. The biggest difference between a medical spa and a non-medical spa is that physicians are not really into pampering. We don't care that much about the way it's done. The emphasis is not on the process itself but the results."

Spas also put an emphasis on results, albeit with lighter forms of treatments. "We pick skin products that have an impact on the skin," says Seven Stones' Powell. "Some people go to Walgreens and purchase products with high expectations." But over-the-counter stores don't sell pharmaceutical-grade cosmetics. And it's these high-end items that really do the job.

"Sure, a dermatologist has a license to play with things we can't," says Powell. "They're physicians and can inject Botox and do chemical peels that take off a heck of a lot more skin surface than we can. Their results are more dramatic. But not everyone needs to go to a doctor's office. Most people just need some good skin advice and a good amount of cleansing."

And that's where spas may be head and shoulders above the medical profession. "We can exfoliate the skin, educate you. I always consider a day spa the first line of defense. We're willing to spend the time and energy working with you, helping you take care of your skin from the beginning so you don't need a medi-spa. If you start early using skin products that protect you from the sun, you won't need more. This is not for the woman who has been sun-worshipping for years and then expects a miracle at a spa. But after she's seen a physician, she can come back to us and we'll educate her about how to maintain that smooth look."

The bottom line is that as long as the esthetician or physician is trained in their area of expertise, it's up to the consumer to choose how light or heavy a treatment they prefer. **M**



## Specialized For Your Special Eyes

The Clear Choice In Eye Plastic Surgeons

- Laser Eye and Forehead Lifts
- Botox®
- Obagi® Skin Care

**Dr. Bruce Massaro, M.D.**

*Board Certified, Fellow American Society of Ophthalmic Plastic & Reconstructive Surgeons*



**Center for Facial Aesthetics**

2600 North Mayfair Road • Suite 600

**(414) 266-4488**

[www.liddoc.com](http://www.liddoc.com)



**We Love Referrals - THANK YOU!**



*Dings Repaired & Hail Too  
While You Wait w/No Paint!  
100% Satisfaction Guaranteed*

**Brookfield**

**196th & Bluemound Rd.**

*Behind Gander Mountain on Janacek Rd. (196th Street)*

**(262) 785-9595**

**Also - Visit Us In:**

**Fox Valley**

**(920) 749-9000**

**Madison**

**(608) 256-9000**

Visit: **[www.IHateDings.com](http://www.IHateDings.com)**

*for more information, maps to locations and coupons.*

MILWAUKEE MAGAZINE DECEMBER 2004 7

# EXHIBIT C

# NS NEOSKIN

LASER HAIR REMOVAL

AFSHIN JAVAHERIAN MEDICAL CORPORATION

ACTUAL PATIENTS

HALF FACE  
OR BEARD  
**\$472.50**

BIKINI  
**\$315**

UNDER ARMS  
**\$315**

CHEST AND  
ABDOMEN  
**\$1,225**

The one time payment covers  
the complete treatment  
(up to 12 Sessions).  
Not valid with any other offer.  
Expire 06 / 30 / 2006

AFSHIN JAVAHERIAN, M.D.

State-of-the-art, painless,  
Laser Hair Removal

**BEVERLY HILLS**  
9730 WILSHIRE BLVD. SUITE 103  
BEVERLY HILLS, CA. 90212  
**(310) 550 8580**

**WESTLAKE**  
3639 THOUSAND OAKS BLVD.  
WESTLAKE VILLAGE, CA. 91362  
**(805) 494 9043**

[www.neoskin.com](http://www.neoskin.com)

+

**Southern Iraq, with its over-**

**Car bombs in other parts of Iraq, including Baghdad, usually are blamed on the Sunni extremist group al-Qaida in Iraq, which has only a small presence in the south. The largest such attack – the coordinated bombing of two ethnic Yazidi**

● To see The Bee's media project 'The Northern Californians who have died in Iraq, go to [www.sacbee.com](http://www.sacbee.com)

**Ali Hussein K**  
he had just finish  
a restaurant wh  
parking lot across

# Canon

SKIN TIGHTENING  
*and*  
CONTOURING  
— without surgery —

  
**Thermage®**  
*Reshaping Your Future*



Pre-Treatment



Two Months Post-Treatment

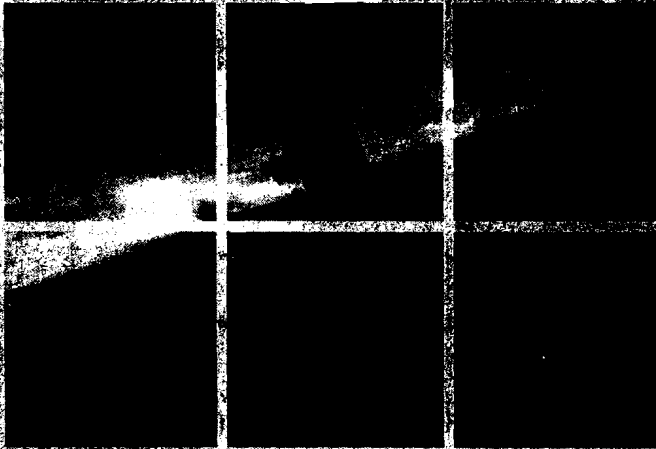
Photos courtesy of Robert Weiss, M.D.

**\$1000  
Off  
Treatment**

for Time Clients Only

**FOR AN APPOINTMENT CALL 341-5555 NOW!**

## Self-conscious about your legs?



**In less than one hour, you could  
be moving in freedom.**

If you have been living with the pain and self-consciousness of **Varicose Veins**, consider **VenaCure**; the safest and fastest vein laser procedure, offered at our comfortable outpatient center in Pasadena.

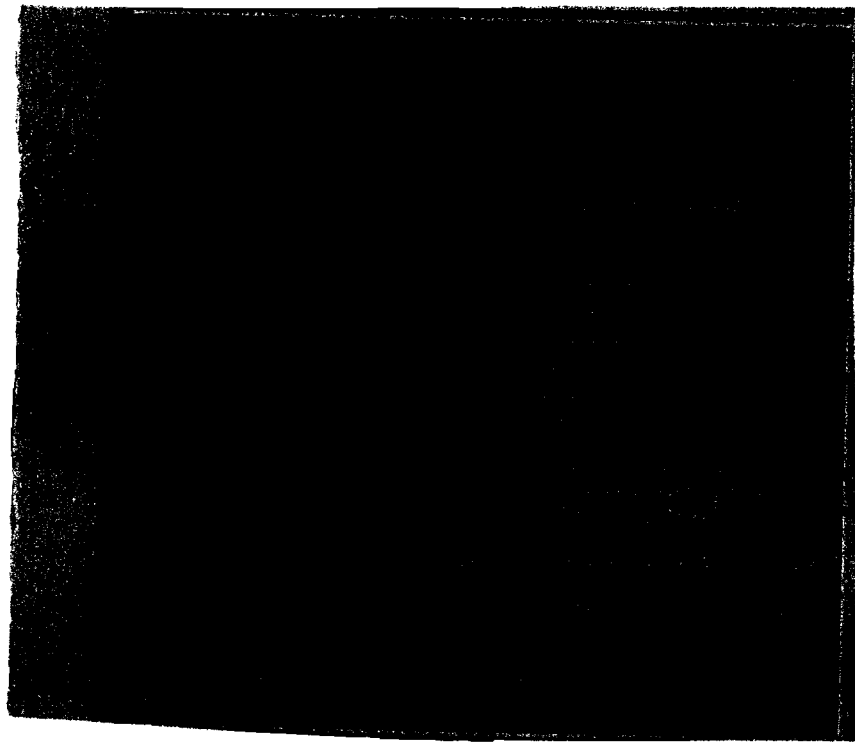
Why wait? The Hill Medical Corporation provides an easier way to remove painful **Varicose Veins** without the use of surgery, and this procedure is covered by most insurance plans. Contact us today. (626) 793-6141.



**THE HILL**  
**BREAST CENTER INC.**

We see the inner you.

50 Alessandro Place, A-30 • Pasadena, CA 91105





LOS ANGELES TIMES

[illegible]

LOS ANGELES  
MAGAZINE

---

DEL. W/REG. STS  
CAND. 15 VOTERS

Do you feel hopeless with side-effects or continue suffering from troubling thoughts and/or voices?

We are a full-service psychiatric hospital specializing in schizophrenia and other mental-health problems conducting an in-patient schizophrenia research study for people who qualify.

You may be able to participate in the studies if you are:  
Between the ages of 18-65 years old.  
Diagnosed with schizophrenia for at least one year by a medical doctor.  
Able to participate as an in-patient for at least 4 weeks.

There is no cost to you:  
You will receive compensation.  
Receive study-related evaluations, study drug or placebo and care.  
No reports are made to employers, schools or insurance.

Please call us at  
1-877-872-7217

US Clinical Research Centers serving Los Angeles and Orange Counties.  
Working Diligently Today On Tomorrow's Cures™

BEFORE

AFTER

BEFORE

AFTER

Have  
Age  
Gotten  
Under  
Your  
Skin??

A truly revolutionary new technology and treatment protocol now allows us to significantly tighten facial and body skin with one non-invasive treatment. Minimal discomfort. No other approach can do this (call us for independent studies that PROVE it). Changes are seen immediately with new advancements.

Our center is a national leader and investigative center. Our director, Dr. Hamilton has appeared on Extra, Good Morning America, ABC World News Tonight, NBC News, etc...

Also available: Fraxel for color & texture rejuvenation, Smooth Glow (beyond IPL & Photo-Rejuvenation), Mesotherapy, and Cellucision (for permanent cellulite treatment); Radiesse instead of Restylane for expression lines (1-2 years typical duration)

procedure, offered at our comfortable outpatient center in Pasadena.

Why wait? The Hill Medical Corporation provides an easier way to remove painful Varicose Veins without the use of surgery, and this procedure is covered by most insurance plans. Contact us today. (626) 793-6141.



**THE HILL**  
BREAST CENTER INC.  
We see the inner you.

50 Alessandro Place, A-30 • Pasadena, CA 91105

Compreh  
laser cen  
Over 20 las  
also featur  
FotoFac  
VelaSmo  
for Celluli  
Microder  
with Ultra  
Vibraden  
with Infusi  
GentleW  
and many m

0% Fin

**BEST**  
**04-05**  
LOS ANGE  
MAGAZINE

**BEST O**  
**PASAD**  
DERMATO  
04-05 Pa

YOU CAN NOW TURN BACK THE HANDS OF TIME AND REGAIN THAT SEXY, YOUTHFUL LOOK WITHOUT RISKY PLASTIC SURGERY!

**OUR FACE AND BODY**  
REJUVENATION PROCEDURES INCLUDE:

**BOTOX®** \$11\*/unit  
Your nonsurgical fine line and wrinkle solutions

**RESTYLANE® OR COLLAGEN** \$450\* per cc  
Age defying facial fillers for fuller sexier lips and smile line reduction

**THERMAGE®** (Face & Neck) \$2450\*  
Non surgical face & neck lift. Tightens arms, hands, thighs, buttocks and abdomen.

**IPL™ Photorejuvenation** (Face) \$295\*+  
For sun damaged skin, rosacea, facial redness, brown spots and fine lines.

**MESOTHERAPY** (per treatment, per area) \$295\*+  
Eliminates problem areas such as double chin, eye bags, tummy bulge, love handles and saddlebags. Smooths out Cellulite.

**PULSED LIGHT HAIR REMOVAL** 20% off\*+  
FDA Approved. For all skin types & colors



**ACNE TREATMENT PROGRAM FOR ALL AGES**

**PHYSICIAN ADMINISTERED WEIGHT LOSS PROGRAM INCLUDING MEDICAL PRESCRIPTIONS**

**BIOIDENTICAL HORMONE REPLACEMENT THERAPY**

**FREE CONSULTATIONS • 0% FINANCING AVAILABLE**

*Advanced Cosmetic & Wellness Center*  
8920 Wilshire Blvd. Suite. 404 • Beverly Hills  
**888.333.2515**

\*First Treatment, New Clients Only. Offer expires 6/30/06. First present Ad. Some Restrictions may apply. Multiple Treatments will be required.

For a free copy of our cosmetic report "looking great at any age:  
A consumer guide to non-surgical procedures"  
Call 1-800-827-1468 and Enter ID# 2103 for a 24 Hour Recorded Message.

C  
Wa  
Fe  
I  
If  
yo  
An  
ye  
I  
No

me

to

# START WITH THE BEST...

Dr. [Name] is a board certified plastic surgeon with over 20 years of experience. He is a member of the American Society of Plastic Surgeons and the American Board of Plastic Surgery. Dr. [Name] has performed thousands of cosmetic procedures, including facelifts, neck lifts, breast augmentation, and tummy tucks. He is known for his expertise in facial rejuvenation and his commitment to providing the best possible results for his patients.



SEE THE PHYSICIAN  
FROM START TO FINISH

- ◆ NONSURGICAL
- ◆ NO TIME OFF WORK
- ◆ AFFORDABLE
- ◆ MINIMAL DISCOMFORT

FREE CONSULTATION WITH THIS AD

AVOID PLAIN VULGARITY  
NEEDLE TREATMENT

HEAVY HILLS, TEXAS  
WEST HILLS, TEXAS

CALL 214-271-1111  
WWW.MEDREPAIR.COM

# EXHIBIT D

<http://www.latimes.com/features/health/la-he-medspas20sep20,1,5927198.story?coll=la-headlines-health>

## Prescription for pampering

**Medical spas are the new hot spots for 'aggressive' skin care. But experts urge caution.**

By Patricia King  
Special to The Times

September 20, 2004

Krista DAVIS is a 34-year-old self-confessed medical spa addict.

Every few weeks, she indulges herself at her favorite medical spa, Sherman Oaks-based Blue. On a typical day, she runs up a tab of \$980 as she moves from manicure to pedicure, to underarm and leg laser hair removal, to Botox and to microdermabrasion, in which mineral crystals are used to sandblast the skin.

It's not cheap, but the Porter Ranch woman, a former aesthetician who now sells skin-care products, feels she gets more bang for her buck at Blue Medical Beauty Spa than she would at a traditional spa, because pampering and "aggressive" medically based beauty treatments are offered under one roof.

And it's under a roof that is far more appealing than an old-fashioned, green-walled doctor's office. Davis loves Blue's futuristic décor, including the big flat-screen televisions, the well-cushioned chairs, the sheepskin rugs and the lush, dark-blue velour curtains. Says Davis, "People don't want to go into a cold setting. They want more inviting settings."

Consumers such as Davis have turned medical spas into the hottest segment of the \$11.1-billion-a-year spa industry. "The spa and the medical world are combining in a new entity," says Eric Light, president of the International Medical Spa Assn. Dermatologists, plastic surgeons and other medical professionals, including dentists and gynecologists, are either opening their own spas or signing on as consultants at existing ones.

But consumer advocates and others worry that regulation of medical spas has not kept up with the industry's growth. The U.S. Food and Drug Administration oversees the safety of the machines and skin-care products used at medical day spas. But it is up to each state to figure out which practitioners can administer the treatments safely.

That job falls mostly to state skin-care and medical licensing boards. But because of explosive growth in the medical spa industry and rapidly changing treatments, those boards cannot regulate medical spas effectively, says industry marketing analyst Nancy Griffin. "As a consumer, you can't count on your state boards to protect you."

Griffin recommends that consumers be in buyer-beware mode when they go to medical spas, because even treatments that are touted as being state of the art can damage the body if performed incorrectly.

Medical beauty treatments can also be pricier than the services at your regular old-fashioned spa. But proponents stress that the prescription-strength products and treatments offered at medical spas are more effective than the body and skin care available at a traditional spa.

Charlie Sheridan, director of the Institute in Marina Del Rey, a medical spa that offers everything from "lipstick to liposuction," says that because the facility's medical director is a plastic surgeon, it can offer pharmaceutical-grade "cosmeceuticals." These prescription products, says Sheridan, are more effective than the skin products available over the counter.

In addition, the Institute offers treatments such as Botox injections; photo facials that use intense light to combat a variety of imperfections, including large pores and age spots; and a face-lift that uses radio frequency energy. Sheridan stresses that these treatments cannot replace surgery, but that "with advanced medical technology, it is quite amazing what can be done. With injectable fillers, peel products and lasers, we can offer amazing improvement."

Manhattan's Juva MediSpa also touts its "physician-formulated spa treatments" that "far surpass the normal spa techniques." For \$135, it offers a 70-minute anti-aging "medical facial" that includes "clinically proven 5-FU [5-fluorouracil, an anti-cancer drug used topically] to remove sun-damaged cells." Says dermatologist Bruce Katz, founder of Juva: "We use medicine in our facials and our body treatments. We put antioxidants into our spa oils."

No matter how "medical" beauty treatments are, insurance companies won't pay for them, which makes for a highly motivated clientele. They're "people who are serious about getting their skin into the most ideal physical and aesthetic condition," says Sheridan. "You have a client population of serious buyers, so to speak."

Cash-based medical spas also provide freedom for doctors who say they are tired of being second-guessed and under-reimbursed by insurance companies. A want ad that appeared recently on the message board of eSTART.com sought "entrepreneurially minded" doctors to work or own a medical spa in New Jersey and New York. The listing, posted by Mobius Development Group, which sells medical spa franchises and consulting services to doctors, stresses "no more hassles with insurance companies."

Dermatologist Mitchel Goldman says chucking the insurance companies he "hates" has enabled him to practice more patient-friendly medicine.

At Goldman's 15,000-square-foot Spa MD in La Jolla, there are soothing waterfalls designed using feng shui and bamboo floors, but there is no waiting room with "20 stupid chairs," as he puts it. Instead, Spa MD features a concierge who directs patients to four nicely upholstered chairs in an area called a reception room. "No one waits. I give people time."

When Goldman was accepting insurance, he packed in 40 to 50 patients a day. "It was like working in a mill." Now, says Goldman, he sees 15 to 20 patients a day. "I'm not going on volume anymore. I'm going on quality."

Doctors can avoid insurance companies at medical spas, but they cannot avoid pricey malpractice insurance coverage. With five full-time and three part-time physicians, 18 nurses, one physician's assistant and one nurse practitioner, Goldman, for example, pays \$250,000 a year in malpractice

insurance.

That's not surprising, given that there have been a number of lawsuits against spas that employ physicians.

In 2001, investment banker Kim McMillon filed a \$125-million lawsuit against the upscale Manhattan-based Greenhouse Day Spa (now under new management), a dermatologist who worked there as a consultant and the cosmetologist who treated her. McMillon, who is African American, alleged she received first- and second-degree burns when the cosmetologist, who she said did not know how to use a laser for hair removal on dark skin, botched the job.

According to the complaint, McMillon halted the treatment halfway through because "I could smell the burning. I could feel my face on fire." McMillon also alleges that the dermatologist incorrectly prescribed a bleaching agent for her burns. The defendants have denied the allegations since the lawsuit was filed. The case is expected to go to trial in the next six months.

McMillon's attorney, Susan Karten, says the case "is really a wake-up call for states around this country" to require that laser hair removal be done by professionals with the proper credentials. Everyone from gynecologists to cosmetologists is performing the procedures, says Karten: "It's a booming phenomenon. Everyone thinks they're an expert."

### **Regulatory confusion**

Would-BE experts are taking advantage of the hodgepodge of regulations that cover laser hair removal and other medical spa procedures.

Some states, for example, require physicians to perform laser hair removal. Others allow physicians to delegate the procedure to medical and nonmedical licensed practitioners as long as they supervise them. A few states have not yet specifically regulated laser hair removal. "It's kind of the wild, wild West," says Dr. Jay Calvert, a UC Irvine plastic surgeon who will be teaching a new course this fall about spas.

The confused regulatory picture means that consumers can become guinea pigs unless they are careful. A weekend training course offered by a company that manufactures lasers does not make a person qualified to remove someone's hair, says Calvert. Before you let someone point a laser at you, make sure you find out how much training and experience they have operating lasers, says Calvert. "You don't want to be part of someone's learning curve."

Some in the medical spa industry are so concerned about lax and conflicting regulations that they are pushing for national standards. Katz says the McMillon case was one of the motivating factors behind his decision to form the nonprofit Medical Spa Society, whose mission is to "promote standards of excellence."

"We don't want a few bad apples to start causing havoc by burning faces," says Katz.

Burned faces aren't the only side effect of botched aesthetic treatments. When the American Society for Dermatologic Surgery queried its members in 2002, 40% of respondents reported seeing more patients who had received substandard care from nonphysicians. Laser treatments topped the list of botched procedures, but the dermatologists also cited chemical peels, acne therapy and misdiagnosis or delayed treatment of skin cancers and rosacea.

According to Dr. Roy Geronemus, a Manhattan dermatologist and former president of the dermatologic society: "We're seeing a lot of scars, superficial burns and changes in pigmentation."

Consumers can sue when they believe they get substandard treatment, just as McMillon did, but most such cases do not end up in court. Some victims shy away from revealing that they received aesthetic treatments. And many lawyers believe that jurors — especially those more concerned about grocery bills and basic medical care than hair and wrinkle-free skin — will have little sympathy for the alleged victims of botched elective procedures.

Although much of the focus on preventing shoddy treatment has been on nonphysicians, industry insiders stress that undertrained doctors can also provide substandard treatment. Susan S. Warfield, chief executive of Paramedical Consultants Inc., a New Jersey-based spa industry consulting firm, warns: "Don't think that because you're going to Dr. Wonderful's medical spa, the aesthetic treatments you're going to be getting are better than Sally's salon and spa down the street."

Goldman agrees. He says consumers should be pushy when asking what type of doctor is involved with the spa. Otherwise, "The doctor could be a proctologist who doesn't know what skin is. All you have to do is have an MD after your name and you can do anything you want."

In addition, consumers need to ask how many hours a week the doctor is at the medical spa. California, for example, allows licensed physician's assistants, nurses and nurse practitioners to perform cosmetic medical procedures, including Botox injections, laser hair removal and intense light facials, if they operate under the supervision of a physician. But Goldman says medical supervision can mean that the doctor is licensed in California but lives in Utah and is at the spa sporadically. Consumers should ask: "Where is the beef? Where is the doctor?"

Karten notes that the Greenhouse Day Spa, where McMillon got her treatment, for example, "billed themselves as having medical oversight." But Karten stresses, "The question is, is that enough?"

Recently, the California Department of Corporations ordered the Los Angeles-based medical spa company HealthWest to "stop offering to sell franchises and licenses." According to the department, HealthWest was advertising that potential franchisees could "own a prestigious business in the medical industry without a medical background."

You don't have to have a medical background to own a spa, but the Department of Corporations says HealthWest failed to get approval before selling franchises and failed to disclose to the franchisees that physician supervision was necessary for some treatments.

## High profits

None of the regulatory loopholes in the medical spa business is likely to put a crimp in its growth, because medical procedures generate high profit for spas. "Laser hair removal as well as photo facials spell higher profit for a medical spa, as opposed to doing wraps and massages," says Calvert.

For doctors, adding spa services can significantly expand their practice, which is why the want ad at eSTART.com touted "increased financial upside," in addition to insurance-free living. At Spa MD, for example, one of four customers who come in for a spa-side treatment eventually wind up as patients on the medical side, perhaps for a treatment for varicose veins.



Medical spas clearly offer a winning business model, but even boosters such as Light say consumers should use common sense when indulging in treatments. "Be realistic about the outcome. Anybody who promises they're going to cure your cellulite or remove every wrinkle on your face, go the opposite way."

Light even recommends that Americans take a more "holistic, European" approach to the aging process: "There's nothing wrong with a wrinkle or two. We used to call them signs of wisdom."

Nonetheless, spa-goers seem bent on wrinkle-free skin. And that is precisely why industry analysts predict a blemish-free future for medical spa profits.

If you want other stories on this topic, search the Archives at [latimes.com/archives](http://latimes.com/archives).

### **TMSReprints**

Article licensing and reprint options

---

Copyright 2004 Los Angeles Times

# EXHIBIT E

# Sacramento DA wins case against skin-care firm's ads

**Skin Nuvo, with services in local malls, is fined but admits to no wrongdoing**

KATRY ROBERTSON / STAFF WRITER

The Sacramento County district attorney's office has won a court judgment against Skin Nuvo International for false advertising.

A Henderson, Nev., company that offers skin care and laser hair-removal services in two Westfield America Inc. malls — Downtown Plaza in Sacramento and the Galleria at Roseville — Skin Nuvo was fined \$22,500 last month and

ordered to pay an additional \$3,000 to cover investigation costs and court fees. A complaint filed Aug. 18 in Sacramento County Superior Court alleged that Skin Nuvo falsely stated in oral and print ads that laser treatments were "painless," "permanent" and "forever."

Laser treatments actually cause long-term hair reduction and delayed regrowth — and many customers require more than one treatment to achieve that.

The misleading ads constitute unfair competition under state law, legal documents allege. The district attorney asked for a court order to prohibit the company from using words that imply the treat-

ment is permanent and require qualifying phrases like "price per treatment" or "prices starting at" in equal size to the price listed in all advertisements.

The final judgment was approved by the court Aug. 20. Skin Nuvo did not admit wrongdoing but agreed to the changes and the fine, said deputy district attorney Justin Puerta. Signed in Sacramento, the court order applies statewide, Puerta said.

Joseph Epps, a Los Angeles attorney who represented Skin Nuvo in the case, could not be reached for comment this week.

The retail skin-care company is expanding aggressively statewide. Skin

Nuvo opened five new locations in the East Bay in April through June, and now has 34 locations in Nevada, California, Oregon and Washington.

Located in shopping centers, the Skin Nuvo stores offer laser hair removal and skin-care services such as microdermabrasion — which mixes gentle abrasion with suction to remove the dead outer layer of skin — plus designer peels, vein therapy, tattoo removal, and Botox and collagen treatments.

Many of Skin Nuvo's services are available on a walk-in basis. The mall setting generates foot traffic, and growing interest in anti-aging treatments brings customers in the door.

# EXHIBIT F

## DECLARATION OF MARISSA RAMOS

I, **MARISSA RAMOS**, declare:

1. I was a summer associate at the law firm Wilke, Fleury, Hoffelt, Gould & Birney, LLP from May 2005 through August 2005. If called to testify, I could competently testify to the following matters.

2. Between July 26, 2005 and August 10, 2005 I called a number of Sacramento and Bay Area medi-spas which offered laser hair treatments, botox injections and collagen lip filler and contouring services. The list of medi-spas to contact was provided to me by Erin E. Weber, an attorney at Wilke, Fleury, Hoffelt, Gould & Birney, LLP. The list contained a total of nineteen medi-spas.

3. On July 26, 2005, I contacted Kaniff Cosmetic Medical Center located at 631 Fulton Avenue, Sacramento California and spoke with Kathy. A physician owns Kaniff Cosmetic Medical Center. In addition, Kathy informed me that Kaniff Cosmetic Medical Center provides many services including laser hair removal, botox injections and collagen lip filler. Each of the aforementioned procedures is performed by a registered nurse. A physician does not directly supervise these procedures as one is not always on the premises.

4. On July 26, 2005, I contacted Sona Laser Center located at 1860 Howe Avenue, Suite 230, Sacramento California and spoke with Kristen. When asked about the ownership of the facility, Kristen responded that Sona Laser Center was a franchise. The franchisee of this location was not a physician, however, a physician oversees the entire franchise in the capacity as a medical director. Sona Laser Center offers laser hair removal, botox injections and collagen lip filler. A physician administers the botox injections and the collagen lip filler. However, a registered nurse performs the laser hair removal. A physician is not always on site when laser hair removal procedures are performed despite the fact that Kristen admitted that the procedure can result in burn injuries.

5. On July 26, 2005 I contacted Accent Esthetics located at 2200 Sunrise Boulevard, Suite 250, Gold River, California and spoke with Terry. Accent Esthetics is physician owned. It offers laser hair removal and botox injections. Both services are undertaken by a registered nurse,

1 although a physician performs the initial botox injection. A physician is not always on site while  
2 these procedures are performed.

3 6. On July 26, 2005 I contacted Eterna Medi-Spa located at 121 Main Street, Suite H,  
4 Turlock, CA and spoke with Lindsey. Eterna-Medi Spa is owned by Dr. Anderson. The spa  
5 provides laser hair removal services and botox injections. All botox injections are performed by a  
6 physician. However, the laser hair removal is done by a registered nurse without any physician  
7 supervision. Indeed, a doctor is only on the premises on Tuesday, Thursday and Friday mornings.

8 7. On July 27, 2005 I contacted Nuvo International located at 1187 Galleria  
9 Boulevard, Suite P126, Roseville, CA and spoke with Tristen. A "medical provider" runs the  
10 facility. The only service a physician does not perform of those discussed (laser hair removal,  
11 botox injections and restylane) was laser hair removal. A registered nurse performs the laser hair  
12 removal without any physician supervision. A physician is only present in the facility a few times  
13 a week.

14 8. On August 10, 2005 I contacted Morphosis Rejuvenation Studio located at 377  
15 Santana Row, Suite 1080, San Jose, California and spoke with Martha. Physician's assistants and  
16 nurse practitioners perform laser hair removal and administer botox injections and collagen lip  
17 filler unsupervised. A medical director oversees the work of the physician's assistants and nurse  
18 practitioners but is not always onsite.

19 9. On August 10, 2005 I contacted the Laser Center of Marin located at 770  
20 Tamalpais Drive, Suite 301, Corte Madera, California and spoke with Karen. The Laser Center  
21 offers laser hair removal, botox injections and collagen lip filler. Both physicians and registered  
22 nurses perform all of these services. A nurse may perform the procedures even when the  
23 physician is absent from the facility.

24 10. On August 10, 2005 I contacted Body Renaissance Skin Care located at 2525 Van  
25 Ness Avenue, Studio F, San Francisco, California and spoke with Mimi. Body Renaissance  
26 offers laser hair removal and botox injections. These procedures are performed regularly by both  
27 a physician and a registered nurse. A nurse may perform the procedures even when the physician  
28 is absent from the facility.

1           12.     On August 10, 2005 I contacted the San Francisco Laser Clinic located at 2215  
2 Chestnut Street, San Francisco, California. The Laser Clinic offers laser hair removal and botox  
3 injections. A physician does the botox injections but a registered nurse performs the laser hair  
4 removal. A medical director oversees the registered nurses administration of the laser hair  
5 removal but is not always onsite as he is an anesthesiologist.

6           13.     On August 10, 2005 I contacted Aneu Professional Skin and Laser Center located  
7 at 2326 Fillmore Street, San Francisco, California. Aneu Professional Skin and Laser Center  
8 offers laser hair removal, botox injections and collagen lip filler services. A physician is not  
9 always in the office when all of the procedures are performed.

10          14.     On August 10, 2005 I contacted ReJuvenate, Inc. and spoke with Ruby. This  
11 medi-spa is located at 805 Veterans Blvd., Suite 140, Redwood City, California. ReJuvenate, Inc.  
12 offers laser hair removal, botox injections and collagen lip filler, contouring and restylane  
13 services. A registered nurse performs all of these procedures. A physician does not provide  
14 direct supervision of these services and is not always onsite as his practice is in a separate  
15 location.

16          15.     I spoke with an individual at the following medi-spas and was told by that person  
17 that a physician is always onsite while procedures are performed:

18                 Laser Esthetica Medical Associates, Roseville California

19                 Laser Advantage of Greater Sacramento, Rocklin, California

20                 Union Street Medspa, San Francisco, California

21                 SKN Medical Spa, San Francisco, California

22                 Aesthetic Skin & Laser Surgery, Walnut Creek, California

23                 Dermatology Laser & Costmetic, Mill Valley, California

24          16.     On August 10, 2005 I contacted Radiant Images Laser Center in Danville,  
25 California. I was unable to ascertain whether a physician was always onsite when services such  
26 as laser hair removal and botox injections are administered.

27          17.     On July 26, 2005, I contacted Skintopia Day Spa in Folsom California. The  
28 individual who answered the telephone indicated that it did not provide any cosmetic medical

1 procedures such as laser hair removal and botox injections.

2 I declare under penalty of perjury under the laws of the State of California that the  
3 foregoing is true and correct. Executed on February 28, 2006 at Sacramento California.

4  
5   
6 MARISSA RAMOS  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28



# EXHIBIT G

[<<Back](#)

The Bay Area's News Station ON AIR &amp; ONLINE

## State Cracks Down on Nuvo International

Posted: June 1, 2005 at 8:45 p.m .

(KRON) -- There are new details in a Contact 4 investigation of so-called medispas -- clinics that looks more like a spa, performing medical cosmetic procedures at malls. We've shown you the graphic evidence: two Bay Area women badly burned by laser hair removal at Nuvo International. Now, Contact 4 has learned the company has declared bankruptcy, just as state officials launch an investigation.

Karin Gilliam hopes a specialist can fix the scars on her face, but inside, her wounds may never heal. "Emotionally inside you just can't measure it. Some days I feel so ugly," she says.

Five months ago, Karin got badly burned by a laser hair removal procedure. She still has scars and white streaks on her face. "I went in looking my best, and I came out looking like Frankenstein."

The same thing happened to Elealah Ruff. "It felt like someone lit a match to my face," she says.

Minutes after her sessions, she noticed a tingling, then a burning. The laser ripped away her skin, leaving it bloody and raw. "It was like black streaks all over my face. I don't know what she did to my face."

Both women are now suing Nuvo International, a chain of medispas you may have seen at your local mall. Just a few weeks after our first investigation the company declared bankruptcy and at Richmond's Hilltop Mall where Karin got burned, Nuvo was shut down.

But many other locations are still open. They're cheaper than a doctor's office. But are they safe?

"They actually asked to see a doctor but there was no doctor available," says dermatologist Dr. Christine Lee. Dr. Lee is a UCSF clinical faculty member and an expert in laser hair removal. She says the biggest problem with medispas like Nuvo is lack of supervision. "If the doctor had been on site and had been able to administer help immediately, probably they would have been able to mitigate a lot of the damages."

Nuvo has 12 clinics in the Bay Area and Sacramento, supervised by three doctors. When we went into Nuvo's Richmond location, there wasn't even a manager around, let alone a doctor.

"We have a person named Karin Gilliam who had some damage done to her face," Contact 4's Joe Ducey said. "Is there a doctor here," he asked. The answer: the doctor wasn't going to be in for another two weeks.

Also, supervising doctor Carolyn Million's primary specialty is colorectal surgery, not dermatology.

Nuvo declined talking to us for this story but earlier told us Dr. Million is qualified to do the job and nurses treating Karin and Elealah did nothing wrong.

Still, the government should crack down, says Dr. Lee. "They are not enforcing the laws, so it's the wild, wild west out there."

"We're spread pretty thin," acknowledges California Medical Board Director Dave Thornton. He says there is just one inspector for every 1,788 doctors. He tells Contact 4 that Nuvo's been under scrutiny, but on the back burner because "medispas are legal."

Nurses are allowed to perform laser treatments if a doctor supervises, and the doctor doesn't have to be on location. "Whether the supervisor visits every day or once a month, we leave it under the discretion of a supervisor," Thornton said.

The law does require the owner of a clinic to be a doctor. Nuvo's owner isn't, but his California franchises are under a medical director's name. That's legal. Critics say it's borderline and they have a name for it: doc in the box.

Reports of serious burns at Nuvo are finally prompting the California Medical Board to take a closer look. "That's what our investigation looks at: what equipment was available, what was the response of the person giving the laser treatment."

Dr. Million is also under investigation. "Her name is a name that has come up. The supervisor is ultimately responsible for what goes on at these locations."

Experts predict Nuvo will be a test case with Elealah and Karin as the posterwomen for a crackdown on the medispa industry.

Still no word on how the bankruptcy proceedings will affect service at nine locations still open in the Bay Area but Contact 4 has learned the company is trying to sell off its assets to a similar medispa chain called Pure Laser Hair Removal and Clinic.

(Copyright 2005, KRON 4. All rights reserved.)



All content © Copyright 2001 - 2005 WorldNow and KRON. All Rights Reserved.  
For more information on this site, please read our Privacy Policy and Terms of Service.

# EXHIBIT H

# Cosmetic Surgery Times


**ADVANSTA**

Where the Exchange on Aesthetic Perspective Begins

[HOME](#) [CONTACT US](#) [CAREER OPPORTUNITIES](#) [PRODUCTS AND SERVICES](#) [SUBSCRIBE / RENEW](#)
**SEARCH**

Whole Site

[E-mail This Page](#)


## Who's managing medspas?

**Advanced Search**
[Home](#)
[Current Issue](#)
[Practice Management](#)
[Physician Profile](#)
[Special Reports](#)
[Archives](#)
[Career Classifieds](#)
[Meetings](#)
[News](#)
[Aesthetic News](#)
[E-News](#)
[New Products](#)
[Columns](#)
[Beyond Beauty](#)
[Legal Insight](#)
[Financial Forum](#)
[On Track](#)
[Tech Wizard](#)
[Clinical Articles](#)
[Anti-Aging](#)
[Blepharoplasty](#)
[Body Sculpture](#)
[Hair Loss or Restoration](#)
[Facial Surgery](#)
[Injectables](#)
[Liposuction](#)
[Reconstruction](#)
[Rhinoplasty](#)
[Other](#)
[Editorial Resources](#)
[Editorial Team](#)
[Customer Service](#)
[Subscriptions](#)
[Advertiser Resources](#)
[Sales Team](#)
[Marketing Services](#)
[Lists](#)
[Reprints](#)
[Digital Ad Specs](#)

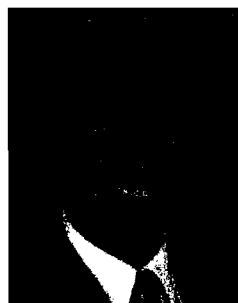
### Lidocaine-induced death raises questions, rallies support for regulations

Apr 1, 2005

 By: [Beth Kapes](#)

Cosmetic Surgery Times

[Order Reuse Permissions](#)  
**RIGHTS LINK**

 Pages | 1 | 2 [more](#)

 Stephen Baker, M.D.,  
D.D.S.

**National report** — A rare incident in which the application of lidocaine prior to laser hair removal resulted in a patient's death has raised serious questions by medical review boards and surgeons about how such a tragedy could occur — and what can be done to prevent future problems.

On Dec. 28, 2004, Shiri Berg, a 22-year-old North Carolina State University senior, suffered a seizure after applying a numbing cream of 10 percent lidocaine prior to her laser appointment. Ms. Berg fell into a coma, dying on Jan. 5. The autopsy report states that she died from an overdose of lidocaine. It also reveals that she suffered heart failure and brain damage.

While initial reports of the student's death caused confusion about how the use of the common drug led to the tragedy, the recently released autopsy report states Ms. Berg wrapped her legs in plastic after applying the drug, in hopes of avoiding the pain caused by the hair removal procedure.

**Fallout from fatalities** The North Carolina Pharmacy Board is investigating Triangle Compounding Pharmacy, the company that sold the compounded lidocaine to Premier Body Laser Clinics in Raleigh, N.C., where Ms. Berg was to have had the procedure. The board also is investigating Premier Body.

"We were surprised by the death (of Ms. Berg), especially since we did not know that the product was being handled in a spa setting," says Steve Hudson, director of investigations and inspections, North Carolina Pharmacy Board. "I don't think this case will impact how lidocaine is formulated, but it will enforce the process of where these products are being maintained and stored," he tells *Cosmetic Surgery Times*.

As a result of the evidence against it, Premier Body Clinic closed its doors Jan. 31, adding fuel to doubts about "medical spas" and the ineptitude of some in performing cosmetic procedures, such as laser hair removal and Botox injections.



Michael McGuire, M.D.

"Every procedure has a potential risk. You need to have someone

**career  
opportunities**



**contact  
us**



who is very knowledgeable in pharmacology and is a trained medical professional to manage the patient," says Stephen Baker, M.D., D.D.S., vice chairman of the American Society of Plastic Surgeons' (ASPS) patient safety committee. "Society has become very complacent about cosmetic procedures, and, as a result, there are many who believe they can perform these procedures regardless of their lack of training. When you put potentially harmful materials in the hands of people who aren't qualified, unfortunate incidents like (Ms. Berg's death) happen."

Draeos, M.D., P.A

**Other cases** On Jan. 25, 2002, Blanco Bolanos of Tucson applied anesthetic cream to her legs and wrapped them in cellophane several hours before a laser hair removal appointment.

After suffering a seizure and living nearly two years in a coma, relying on a respirator, Ms. Bolanos died on Nov. 1, 2004.

"These incidents underline the importance of a medical spa truly being under the direction of a medical practitioner," says Michael McGuire, M.D., public education chairman for the American Society for Aesthetic Plastic Surgery (ASAPS). "So many times, procedures performed in medspas are done by unlicensed personnel who are supposedly acting under the authority of the physician, but indeed the physician doesn't know what's going on."

If a physician truly supervises a spa, then the physician needs to be there at all times to oversee the patient, contends Zoe Diana Draeos, M.D., P.A., clinical associate professor, department of dermatology, Wake Forest University, Winston-Salem, N.C.

Pages | 1 | 2 [more »](#)

#### About the Author

#### Beth Kapes

[About Beth Kapes](#)

[See more articles by Beth Kapes](#)

 **Print**



[About](#) | [Contact](#) | [Patient Edition](#) | [Survey Results](#) | [Privacy Policy](#)

© 2005 Advanstar Communications. All rights reserved.

Reproduction in whole or in part is prohibited.

Please send any technical comments or questions to our webmaster.

# Cosmetic Surgery Times

Where the Exchange on Aesthetic Perspective Begins

Need more freedom...

[HOME](#) [CONTACT US](#) [CAREER OPPORTUNITIES](#) [PRODUCTS AND SERVICES](#) [SUBSCRIBE / RENEW](#)

## SEARCH

Whole Site

 [E-mail This Page](#)


## Who's managing medspas?

## Advanced Search

[Home](#)[Current Issue](#)[Practice Management](#)[Physician Profile](#)[Special Reports](#)[Archives](#)[Career Classifieds](#)[Meetings](#)[News](#)[Aesthetic News](#)[E-News](#)[New Products](#)[Columns](#)[Beyond Beauty](#)[Legal Insight](#)[Financial Forum](#)[On Track](#)[Tech Wizard](#)[Clinical Articles](#)[Anti-Aging](#)[Blepharoplasty](#)[Body Sculpture](#)[Hair Loss or Restoration](#)[Facial Surgery](#)[Injectables](#)[Liposuction](#)[Reconstruction](#)[Rhinoplasty](#)[Other](#)[Editorial Resources](#)[Editorial Team](#)[Customer Service](#)[Subscriptions](#)[Advertiser Resources](#)[Sales Team](#)[Marketing Services](#)[Lists](#)[Reprints](#)[Digital Ad Specs](#)

### Lidocaine-induced death raises questions, rallies support for regulations

Apr 1, 2005

By: [Beth Kapes](#)

Cosmetic Surgery Times

[Order Reuse Permissions](#)  
**RIGHTSLINK**
[« back](#)
[Pages | 1 | 2 »](#)

"There's been a relaxation of where laser hair removal is being performed, and other procedures such as leg veins that are being treated by nonmedical personnel in leg vein clinics," Dr. Draelos says.

She says the issue surrounding these deaths goes beyond nonmedical individuals performing cosmetic procedures. In some cases, she says, the procedures are performed by nonspecialty professionals.

"The North Carolina phone book cover advertises a foot surgeon who performs Botox injections. What is an orthopedic surgeon doing injecting Botox into people's faces to alleviate wrinkles?" Dr. Draelos asks. "The reason I have a medical degree in my specialty is that when problems arise, I know how to deal with them — and I know how to prevent them."

**Regulating risk** While lidocaine is not a controlled substance, the topical medication should be taken just as seriously. It is known to have potential toxicity, yet there isn't as great an appreciation for its application as there should be, according to Dr. McGuire.

"Part of the problem is that the absorption of topicals is so variable. Lidocaine levels that we talk about are based on studies that were done 40 to 50 years ago, with most 'safe' levels being based on epidural injections," he says.

"Even when discussing injecting very diluted lidocaine into subcutaneous fatty tissues for liposuction, there was a great debate if this was a safe level. It turned out that a much higher level was safe when injecting lidocaine in this way. We're a long way from understanding what the safe level is for topical lidocaine applications."

It's important to remember that even correct concentrations can lead to systemic reactions, says Peter Aronson, M.D., assistant professor of dermatology, Wayne State University, Detroit.

"I have seen more than a few systemic reactions to topicals, and most of the time they seemed surprising to me, yet in truth, most had been reported in the literature before," Dr. Aronson says. "I have seen allergic reactions to one drop of a topical sulfacetamide under a nail that led to a generalized rash, a topical EMLA that led to angiodema, and



MEDICAL

**AD**  
THE JOURNAL
**H**  
**Edu**
**Nob**  
**more**  
**to y**  
**educat**  
**than**  
**He**

**career  
opportunities**

topical clindamycin in three of my patients was associated with diarrhea."

Although the concentration and formulation may have been correct in the North Carolina case, Ms. Berg's death underlines the fact that many are not heeding U.S. Food and Drug Administration regulations forbidding the dispersal of drugs such as lidocaine by spas that are not overseen by a medical professional.

Some speculate that in North Carolina, the medical board will enforce tighter regulations that would ultimately shut the doors of other spas like the Premier Body Clinic, and surgeons concur that a nationwide effort should follow.

**contact  
US**

Concern is growing due to the deaths in North Carolina and Arizona, with movements afoot in Michigan to keep the supervision (of medspas) strict and not loose, as apparently is the case in other states, according to Dr. Aronson.

"It's not a question of the medication, it's the question of the application of the medication," Dr. Baker says. "Unfortunately, people do not react until there is adverse sequela."

« back


Pages | 1 | 2 more »

#### About the Author

#### **Beth Kapes**

[About Beth Kapes](#)

[See more articles by Beth Kapes](#)

 **Print**



[About](#) | [Contact](#) | [Patient Edition](#) | [Survey Results](#) | [Privacy Policy](#)

© 2005 Advanstar Communications. All rights reserved.

Reproduction in whole or in part is prohibited.

Please send any technical comments or questions to our webmaster.



# EXHIBIT I

### **Medical Spas (Article for Action Report's Consumer Corner):**

Medical Spa. It sounds so soothing. It evokes images of candles, beautiful music, warmth and papery. Spahhhh! The word itself makes one relax.

Medical Spas are marketing vehicles for medical procedures. The use of the term "spa" is for advertising purposes to make the procedures seem more appealing. In reality, however, they're the practice of medicine.

There's no harm in seeking pampering or in wanting to look better. A visit to a spa may provide a needed respite from our stressful lives, and treatments that makes us look better often makes us feel better. Those of us at the Medical Board, however, become concerned when medicine is marketed like a pedicure, and consumers are led to believe that being injected, lasered, and resurfaced requires no more thought than changing hair-color.

Wrong. Medical treatments should be performed by medical professionals. There is risk to any procedure, however minor, and consumers should be aware of the dangers. While it is illegal for non-licensed personnel to provide these types of treatments, consumers should know that there are persons and firms operating illegally. Cosmetologists, while licensed professionals and highly qualified in superficial treatments such as facials and microdermabrasion, may never inject the skin, use lasers, or perform medical-level dermabrasion or skin peels. Those types of treatments must be performed by qualified medical personnel. In California, that means a licensed physician, or a licensed registered nurse or physician assistant under the supervision of a physician.

Patients must know the qualifications of those they are trusting with their health. Those seeking cosmetic procedures should know that the person performing them is medically qualified and experienced. Specifically, patients should:

- 1) Know who will perform the procedure and their licensing status:

If a physician is performing the treatment, you should ask about his or her qualifications. Is the doctor a specialist in these procedures? Is he or she board certified in an appropriate specialty? Licensing status may be verified at the Board's website: [www.mbc.ca.gov](http://www.mbc.ca.gov). Board certification status may be verified at [www.abms.org](http://www.abms.org).

If a nurse or physician assistant will be doing the procedure, what are their qualifications? Where is the doctor supervising them? Are they really being supervised, or are they acting alone with a paper-only supervisor? Again, you should check the supervising doctor's credentials, as well as the nurse's or physician assistant's. Those websites are [www.rn.ca.gov](http://www.rn.ca.gov) and [www.physicianassistant.ca.gov](http://www.physicianassistant.ca.gov).

An appropriate examination must be conducted before treatments are performed. This exam must be conducted by a physician, or the doctor may delegate the

examination to licensed nurse practitioners or physician assistants. Physicians may not delegate this examination to registered nurses.

2) Be fully informed of about the risks:

All procedures carry risks, and conscientious practitioners will fully disclose them. Medical professionals have an ethical responsibility to be realistic with their patients and tell them what they need to know. If procedures are being heavily marketed, with high-pressure sales techniques promising unrealistic results, run.

3) Observe the facility and its personnel:

Medical procedures should be done in a clean environment. While one cannot see germs, one can see if the facility looks clean and personnel wash their hands, use gloves, and use sound hygienic practices. If you observe dirty conditions, or notice that the personnel does not wash their hands before approaching you, find another facility.

4) Ask about complications, and who is available to handle them:

In the event you should have an adverse reaction, you want to know who will be there to help. Who should you call, and what hospital or facility is available where the doctor can see you? If you get an unsatisfactory answer that minimizes your concerns, or they don't have an answer, find someone else. Qualified physicians have facilities or privileges at hospitals where they can handle emergencies. If they don't, that's cause for concern.

5) Don't be swayed by advertisements and promises of low prices:

There are a host of medical professionals offering competent, safe cosmetic procedures. If they are being offered at sub-standard prices, there's a good probability that what they are advertising is not what will be delivered. Genuine Botox, Collagen, Restalyne, and other injections are pricey. If someone is offering an injection for \$50, when the going rate at doctors' offices is \$500, then you can be sure it's not the real McCoy. There have been tragic cases of unscrupulous practitioners injecting industrial silicone and toxic counterfeit drugs that have made patients critically ill, caused disfigurement, or killed them.

Cosmetic procedures, at best, can boost one's mood and appearance. At worst, they can kill you. Don't trust your health, your skin, or your face to the unqualified or unscrupulous. Know that there is a substantial financial cost to obtaining qualified treatments, as well as some risk. If you want the best results, do your homework and only trust those who demonstrate competence and caution.

## **The Bottom Line: The Business of Medicine – Medical Spas**

There has been an explosion of cosmetic medicine over the past years, and many physicians are being approached to "increase their bottom line" by entering into this lucrative field. Recently, our office received a letter from a business promoting the many programs they offered to physicians that contained the following message:

"... Lastly, we are very excited to announce our Medical Director program. This opportunity allows Doctors and Physicians to earn up to \$400 per month per spa in their area. We have several DaySpas that anxiously await a Medical Director and we would anticipate a large number of client referrals to your practice.'.....'We would be happy to discuss how they can benefit your practice and grow your bottom line.'"

What this business is offering is the opportunity for a physician, for a fee, to rent their license to a business so that they may engage in the practice of medicine --- a profession for which they have no license or qualifications.

Is what they propose legal? Can physicians simply sign-on, lend their name on paper to a salon or spa, collect "up to" \$400 a month, and escape any liability or responsibility for the patients treated by the business? NO!

In 2006, Senator Liz Figueroa authored legislation (SB 1423, Chap 873) that directed the Medical and Nursing Boards to work together to study the issue of safety in the use of lasers in cosmetic procedures. Over the past year, the boards have been holding public forums on the subject. What we have learned is that the current law is being violated with impunity by many in the cosmetic medical field.

The current environment gives rise to violations of the laws governing the business of medical practices, including violations of the corporate practice bar, as well as fee-splitting and payment for referrals. The illegal business models give rise to the use of non-licensed or inappropriately licensed personnel, paper-only supervision (rent-a-license) of allied health professionals, consumer confusion over the medical nature of the procedures, and confusion over who is responsible for the patient. Patients are not fully informed of the risks and often do not know the medical nature of the treatments or who is responsible for their care.

**The use of prescriptive medical devices and injections for cosmetic reasons is the practice of medicine:**

There is a tendency for the public, and some in the profession, to view laser treatments, Botox and cosmetic filler injections as cosmetics, rather than medical treatments. The use of prescriptive drugs and devices, however, is the practice of medicine, and the same laws and regulations apply to these types of treatments as those driven by medical necessity. There are no separate laws governing these procedures, and physicians will be held to the same standard as they are for their routine medical practices. This means that the standards for informed consent, delegation to allied health professionals, physician-patient confidentiality and boundaries, maintaining medical records, as well as responsibility and liability apply to physicians.

### **Physician responsibility in the delegation to allied health professionals:**

In the practice of medicine in all specialties, physicians routinely delegate functions to allied health professionals. In delegating anything to others, physicians must only delegate to appropriately licensed staff that they know to be capable of performing the task. The use of lasers and other prescriptive devices and prescriptive drugs must only be performed by licensed registered nurses, nurse practitioners, or physician assistants. No unlicensed staff, such as medical assistants, may use these devices or drugs, regardless of the level of training or supervision. Likewise, delegation to improperly licensed personnel, such as estheticians, is prohibited.

### **Supervision of those to whom procedures are being delegated:**

While current law allows the delegation of laser treatments and injections to the above mentioned licensees, the law requires supervision by the physician. In the current environment, many have operated under the misguided opinion that since the nursing regulations are broadly written, nurses may perform anything anywhere with essentially no supervision as long as there is "standardized procedures" or "delegation of services" documents on file.

#### Nurses:

Standardized procedures for nurses allow procedures to be performed while the physician is not on-site, however, they do not absolve physicians from their supervision responsibilities. Nor does the law allow nurses to set-up a practice in a salon, hire a physician supervisor, and perform medical procedures independently.

The law does not contain a legal definition of supervision, and therefore, absent a legal definition, the plain English definition applies. "Supervision" is defined as the act of supervising, which is to oversee, to direct, to have charge, to inspect, to provide guidance and evaluation. The law and regulations support this definition.

As an example, the regulations for "standardized procedures guidelines" require physicians be responsible for ensuring the experience, training, and education requirements for performance of the delegated function – and documented, and that a method of initial and continuing evaluation of the nurses' competence be established. Further, it is the responsibility of the physician to examine the patient before delegating the task to a registered nurse.

When functioning under "standardized procedures," physicians need not be present in the facility when the procedures are being performed. The facility, however, must be a medical setting. Regulations require that the location be an "organized healthcare system," which is not a salon, spa, or other facility not under the control of the physician.

An appropriate prior examination is required for all prescriptive drugs and devices, and the examination may not be delegated to registered nurses. After performing the examination, the supervising physician may delegate the procedure to a nurse working under standardized procedures.

The guidelines further require that circumstances be articulated "which the registered nurse is to immediately communicate with a patient's physician concerning the patient's condition." While there is no actual mileage limit in the law relating to supervision, this requirement certainly means that the physician must be immediately reachable and able to provide guidance in the event of an

emergency or the need for a higher-level of care that must be provided by the physician. Physicians must be within a geographical distance which will enable them to effectively provide supervision and support when needed.

For more specific information on registered nurse and nurse practitioner regulation, the Board of Registered Nursing website is: [www.rn.ca.gov](http://www.rn.ca.gov).

#### Nurse Practitioners:

Nurse Practitioners are granted much more autonomy than registered nurses. They are advance practice nurses who are master-level educated, and, for that reason, have a broader scope of practice than registered nurses. The major exception to the rules governing their supervision in cosmetic procedures is that they may be delegated the task of providing the "appropriate prior examination" and order the drug or prescriptive device for the patient, if acting under "standardized procedures."

#### Physician Assistants:

The supervision of Physician Assistants is similar to that of nurses', however, their regulations are much more specific. First, PAs may only be delegated tasks that are part of the physician's customary practice. In other words, obstetricians may supervise PAs treating obstetrical patients; pediatricians may supervise PAs providing care to pediatric patients, and so forth. Therefore, if cosmetic medicine is not a part of the physician's customary practice, the physician may not supervise a PA providing cosmetic procedures. In addition, physicians may only supervise four PAs at any moment in time, and must be in the facility with the PA or be immediately available by electronic communication if they are working under a delegation of services agreement.

PAs may be delegated the "appropriate prior examination" of the patient, but there are methods enumerated in the law and regulations on how physicians must provide their supervision and evaluation. For more specific information, all of the rules and regulations are available at the Physician Assistant Committee website: [www.pac.ca.gov](http://www.pac.ca.gov).

#### Supervision of all allied health professionals:

"Supervise" is a verb, and it requires those calling themselves supervisors to act by supervising, which is to guide, direct, oversee, and evaluate performance. Physicians must really supervise, not lend their license to allied health professionals on paper without providing any supervision. A physician who is, on paper, a supervisor, who does not give direction, oversee or inspect, is not performing the task of supervising, and is in violation of the law.

#### **Qualifications of Physician Supervisors:**

Physicians may only delegate to those that they know to be capable of performing the task. If they are to supervise the procedure, the physician too should be capable of performing it. One cannot provide guidance, direction, evaluation and oversight unless one is knowledgeable and competent in the procedure being delegated.

The law does not require board certification to perform cosmetic procedures. That said, however, one should not think that the absence of this requirement allows anyone of any specialty to

supervise cosmetic procedures, unless the physician has sufficient knowledge and training in the procedures being performed --- by the physician or delegated to others under his or her supervision.

### **Business arrangements; issues of ownership and control:**

California law prohibits the corporate practice of medicine. Laypersons or lay entities may not own any part of a medical practice. (Business & Professions Code Section 2400) Physicians must either own the practice, or must be employed or contracted by a physician-owned practice or a medical corporation. (The majority of stock in a medical corporation must be owned by California licensed physicians, with no more than 49% owned by other licensed health care professionals, such as nurses, physician assistants, nurse practitioners, etc. No stock in a medical corporation may be owned by a lay-person. (Corporation Code Section 13401.5(a))

In an attempt to circumvent this legal prohibition, some have created business and management schemes that violate the law. Businesses that provide management services, franchises or other models that result in any unlicensed person or entity influencing or making medical decisions is in violation of the law.

As an example, businesses that control medical records, the hiring and firing of healthcare staff, decisions over coding and billing, and the approving or selection of medical equipment or drugs, violate the law. Management Service Organizations (MSO) arranging for advertising, or providing medical services rather than only providing administrative staff and services for a physician's medical practice (non-physician exercising controls over a physician's medical practice, even where physicians own and operate the business) would also be illegal. Also, many current business arrangements violate the prohibition against fee-splitting or giving any consideration for patient referrals. The current practice of lay-owned businesses hiring medical directors is also prohibited.

Physicians who become employees or contractors of lay-owned spas and violate other business provisions of the laws may be disciplined for unprofessional conduct.

### **Physician Responsibility for back-up systems and emergency plans:**

Physicians performing or delegating treatments are responsible for their patients' care. As supervisors, they are responsible to ensure back-up systems and emergency plans. Under current law, the patients are the physicians' responsibility, and they are responsible for treating mishaps, complications or any other emergency that might arise from the treatments they delegated. While nurses are responsible for their patients within their scope-of-practice, under the Medical Practice Act, physicians have the ultimate responsibility for the care of their patients.

### **Physician responsibility for patient informed consent and education:**

All medical procedures must be preceded by informed consent, which should include the possible risks associated with the treatment. While there is no specific code that enumerates what must be told to patients, the well-established doctrine of informed consent in case law requires that patients must be, at a minimum, informed of:

- 1) the nature of the treatment,
- 2) the risks, complications, and expected benefits, including its likelihood of success, and

- 3) Any alternative to the recommended treatment, including the alternative of no treatment, and their risks and benefits.

Providing sufficient information to constitute informed consent is the responsibility of the physician.

### **Physician responsibility for advertising and marketing:**

California law requires advertising to include the physician's name, or the name for which they have a fictitious name permit. (Business & Professions Code Section 2272) While the nurses may be performing the treatment, the name of the supervising physician, or his or her registered fictitious name, must be in the advertisement.

The law governing physician advertising is specific, and requires the physician ads not be misleading. California law is very specific in prohibiting many of the advertising practices currently being used to promote cosmetic treatments. The use of models, without stating that they are models, the use of touched-up or refined photos, and claiming superiority of the facility or procedures with no objective scientific evidence is prohibited. Also, the use of discount or bait and switch promotions is also not allowed. The use of "for as low as" in advertising procedures, is strictly prohibited. The laws relating to physician advertising, Business & Professions Code Section 651 may be viewed on the Medical Board's website: [www.mbc.ca.gov](http://www.mbc.ca.gov).

### **The Bottom Line:**

Cosmetic procedures are the practice of medicine, and physicians are responsible for their patients, regardless of who performs the treatments. There is no legal scheme that allows physicians to collect a fee for signing their name to an agreement to lend their license to an entity to practice medicine. Legally, the "clients" of the spa or salon are patients --- the *physician's* patients, and that arrangement comes with all of the responsibility and liability that goes with any other doctor-patient relationship. Becoming involved in these types of business arrangements, may, in the short term, raise a physician's economic bottom line. In the long run, however, the risks are great. In reality, the bottom line is that physicians who become embroiled in these illegal arrangements may lose their license, or their livelihoods.

*It is impossible to cover all of the relevant legal issues in this short article, and the content is not a substitute for professional legal advice. Physicians may want to consult with their attorneys or malpractice carriers for additional legal advice.*



**MEDICAL BOARD STAFF REPORT**

DATE REPORT ISSUED: February 1, 2008  
SUBJECT: Review of Laser Use per Section 2023.5 of the  
Business and Professions Code  
STAFF CONTACT: Janie Cordray

**REQUESTED ACTION:**

- 1) Approve the two attached statements for publication and distribution (Attachments C and D).
- 2) Continue to support the reestablishment of Operation Safe Medicine to assist with the investigation of these cases and encourage staff to increase the use of the citation and fine process to act as a deterrent for these violations.

**STAFF RECOMMENDATION:**

Staff recommends that the Board approve the two prepared statements. The first is a statement outlining the responsibilities of physicians in cosmetic procedures, including the supervision of allied health staff performing laser procedures. The second is a statement to better inform consumers on cosmetic procedures. In addition, staff is recommending the Operation Safe Medicine Unit, once reestablished, investigate these matters and increase the use of citations.

**EXECUTIVE SUMMARY:**

SB 1423 (Figueroa; Chap. 873, Stats. of 2006) added section 2023.5 to the Business & Professions Code, which requires the Medical Board and the Board of Registered Nursing, in consultation with the Physician Assistant Committee, to examine the issues surrounding the use of lasers in cosmetic procedures and patient safety.

Medical Board and Nursing Board staff held three public forums to solicit comments from physician, nursing, and physician assistant organizations, the laser industry, and patients, among others. The meetings were chaired by members of both boards, including Drs. Mary Moran and Janet Salomonson of the Medical Board.

Following consideration from testimony at the three forums and analysis of the laws and regulations that relate to cosmetic procedures and the delegation of procedures to allied health professionals, staff is not recommending regulatory action at this time. Staff believes that after reestablishment of the Operation Safe Medicine Unit and reviewing the impact of the citation and fine process, the board will be in a stronger position to make recommendations regarding any future legislative/regulatory action, e.g. increased fine amount, supervision definition, etc.

**FISCAL CONSIDERATIONS:**

No additional fiscal considerations at this time.

**PREVIOUS MBC AND/OR COMMITTEE ACTION:**

At the November 2007 Board Meeting, the Members approved the reestablishment of the Operation Safe Medicine Unit.

Attachments

A – Memo summarizing the laser forums

B – Memo analyzing current laws and regulations on the use of lasers and background information

C – Article regarding physician responsibility

D – Article for consumers

**Medical Board of California**

January 7, 2008

**TO:** Members,  
Medical Board of California

**FROM:** Janie Cordray,  
Research Director

**SUBJECT:** SB 1423 (Figueroa; Chap. 873, Stats. of 2006) – Medical Board's  
Responsibility to Review Laser Safety in Elective Cosmetic Procedures;  
Report on Laser Forums

SB 1423, which (Figueroa; Chap 873, Stats. of 2006) added section 2023.5 to the Business & Professions Code, directs the Medical Board of California and the Board of Registered Nursing to review the issues of the safety of lasers in elective cosmetic procedures.

Section 2023.5 provides:

*(a) The board, in conjunction with Board of Registered Nursing, and in consultation with the Physician Assistant Committee and professionals in the field, shall review issues and problems surrounding the use of laser or intense light pulse devices for elective cosmetic procedures by physicians and surgeons, nurses, and physician assistants. The review shall include, but need not be limited to, all of the following:*

- (1) The appropriate level of physician supervision needed.*
- (2) The appropriate level of training to ensure competency.*
- (3) Guidelines for standardized procedures and protocols that address, at minimum, all of the following:*
  - (A) Patient selection.*
  - (B) Patient education, instruction, and informed consent.*
  - (C) Use of topical agents.*
  - (D) Procedures to be followed in the event of complications or side effects from the treatment.*
  - (E) Procedures governing emergency and urgent care situations.*

*(b) On or before January 1, 2009, the board and the Board of Registered Nursing shall promulgate regulations to implement changes determined to be necessary with regard to the use of laser or intense pulse light devices for elective cosmetic procedures by physicians and surgeons, nurses, and physician assistants.*

**Review of Issues – Information Gathered at Public Forums:**

To begin to conduct the mandated review of issues, the Medical and Nursing Boards decided to hold three public forums to solicit comment on the safety of the use of lasers in cosmetic procedures.

In preparation of the Forums, Medical Board and Nursing Board staff met to discuss the issues relating to the current environment of cosmetic laser practice. Staff noted that the environment of laser practice was often not safe or legal, and, specifically, had observed the following problems:

- Ownership violations of "Medical Spas" or combined cosmetic & medical practices;
- Corporate practice violations: the employment of a "Medical Director, "Collaborative Physician" or "Supervising Physician";

- Fee-splitting, paying for referrals, and a number of business schemes designed to circumvent the prohibition of hiring physicians;
- Remote or absent supervision;
- Use of non-licensed, or inappropriately licensed personnel;
- Consumer confusion as to the medical nature of laser procedures and issues of liability;
- Potential for patient harm.

As a result of the forums, held in Santa Ana, Sacramento, and San Diego on August 31, September 13, and October 31, board members and staff have heard from a number of interested parties. Those who made formal presentations were:

- American Academy of Cosmetic Surgeons
- American Laser Centers
- American Association of Medical Esthetic Nurses
- American Society of Cosmetic Dermatology & Aesthetic Surgery
- California Academy of Cosmetic Surgeons
- California Academy of Facial Plastic and Reconstructive Surgeons
- California Academy of Physician Assistants
- California Association of Nurse Practitioners
- California Nursing Association
- American Society of Dermatological Surgery
- California Society for Dermatological Surgery
- California Society of Dermatologists
- California Society of Plastic Surgeons
- Norm Davis, J.D., Healthcare attorney
- Christine Lee, M.D., Dermatologist
- Lumier Medical, Inc.
- Stephen Moore, Patient Advocate
- Alan Voss, A. L. Voss, Associates, Medical Device Consultant

(Minutes of all three forums are available on the Board's website.)

In addition to the formal presentations made by these individuals and organizations, a number of persons offered comment, including individual nurses, physicians, physician assistants, and consumers.

The presentations made by the various professional associations echoed the problems discussed by staff. Testimony demonstrated that there is frequent disregard of the law in the use of these devices in the treatment of patients. In addition to highlighting the problems of the industry, there were a number of recommendations voiced by those offering testimony, including:

- Increase the definition of medical practice and medical offices or settings.
- Better define the span of control over sites, and possibly limit the number of persons supervised.

- Accredit or certify locations or sites of the procedures.
- Increase supervision of RNs, requiring the same for RN's standardized procedures as for physician assistants.
- Set minimum standards for training, and perhaps require some kind of certification and examination requirement for the use of the devices.
- Establish certification or accreditation requirements for the training courses.
- Close any loopholes in the standardized procedure guidelines of nurses.
- Promulgate regulations to define lay-involvement and corporate practice.
- Require that the supervising physician be on-site, or available via telecommunications at all times during the procedures.
- Allow delegation of tasks or procedures only consistent with the supervising physicians' specialty or "usual or customary practice."
- Require physician supervisors to review and examine the nurse's performance.
- Established back-up procedures and emergency plans.
- Require physicians do a skin exam before any laser treatments.
- Only allow laser treatments in medical settings.
- Enforce the current laws and regulations.

#### **Medical Board Jurisdiction:**

While the law requires the Medical and Nursing Boards to jointly study the issues and consult with the Physician Assistant Committee, any proposed regulations would be heard separately by each board or committee. The Nursing Board, Physician Assistant Committee and the Medical Board only have jurisdiction over and can only impose regulations on their licensees. For that reason, the Board must focus on the issues relating to physicians and their responsibilities, including their responsibilities as supervisors of allied health professionals.

#### **Discussion of Future Actions of the Boards:**

The public forums held jointly by the Medical and Nursing Boards have accomplished their purpose of gathering information. The Boards now have a greater understanding of the issues, how practices are violating current law, the risks of injury, the lack of knowledge of licensees and patients, and how the lack of enforcement may have contributed to the risks and violations.

It appears there may be no need for further laws or regulations; however, there is a need for more resources for enforcement to proactively address the issues. The development of a strategy or method to enforce current laws should precede any efforts to seek any additions or amendments without obtaining further resources and commitment to their enforcement. (See following memorandum, "Current Laws Relating to the Use of Lasers and Their Enforcement.")

By law, the members are directed to review the issues relating to laser safety and take actions they deem necessary by January 1, 2009. This matter is scheduled for discussion at the Board meeting on February 1, 2008.